An exploratory study of healthcare technology development using a Lean thinking perspective

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I confirm that the word count of this thesis is less than 100,000 words.

Contents

List of Figures

List of Tables

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Abstract

The use of Lean in healthcare as an improvement approach is commonplace with the results being widely reported in operational and academic literature. Despite the prevalence of Lean as an improvement approach, healthcare remains in a position of crisis which raises questions about the appropriateness of the historic approaches for Lean. In parallel the growing influence of technology to improve healthcare is evident with operational and policy decisions reflecting an ongoing appetite to improve healthcare through technology. This thesis analyses Lean literature to understand the use of Lean and technology in healthcare for patients. It focuses on the growing ageing population with long term conditions prior to creating a high-level value stream map for cardiovascular patients from Northern Ireland. This exploratory research utilised available open data sources and expert focus groups over a 5-year period to develop a Lean healthcare technology model as a contribution to Lean knowledge. The thesis identifies that Lean healthcare is focused on providers and not patients leading to unmet value for patients and system level non-value add activities across the patient journey. A Lean healthcare technology model can be utilised to identify and address both patient value and non-value add activities. A number of propositions are presented which provide a platform for further studies of other long-term conditions beyond cardiovascular disease which are likely to benefit from a similar research methodologies. Future studies could also extend the research beyond public health care systems to private healthcare systems as the literature highlights similar Lean healthcare failures in other geographies.

The findings will assist operational, strategic and healthcare academics implementing healthcare reform. Healthcare managers should consider the role for technology and Lean to address wastes across the current silos to improve healthcare outcomes and address wasted resources in resource constrained organisations.

Abbreviations

ABPI – Association of the British Pharmaceutical Industry

AF - Atrial fibrillation

AHSN – Academic Health Science Network

ALOS - Average Length of Stay

AMR – Antimicrobial Resistance

BNF – British National Formulary

BSO – Business Services Organisation

CDC - Centre for disease control

CHF – Congestive Heart Failure

CNA – Could Not Attend

COO – Chief Operating Officer

CTO – Chief Technical Officer

DNA – Did Not Attend

ED – Emergency Department

EHR – Electronic Health Record

GP – General Practitioner

HF – Heart Failure

HSC – Health and Social Care (Northern Ireland NHS)

IOT – Internet of Things

LoRa – Long Range (Type of LPWAN)

LPWAN – Long Powered Wide Area Network

LTC – Long Term Conditions

LV – Left Ventricle (Heart Function Measurement)

MOIC – Medicines Optimisation Innovation Centre

NYHA - New York Heart Association

QALY – Quality Adjusted Life Years

QOF – Quality Outcomes Framework (GP Payment Measurement)

PACS – Patient Archiving System

PDSA – Plan Do Study Act

POCT – Point of Care Testing

QUB – Queens University Belfast

SBRI – Small Business Research Initiative

SMED – Single Minute Exchange or Die (Changeover time)

RIE – Rapid Improvement Events

RCT – Randomised Control Trial

STP - Sustainability and Transformation Plan

UTI – Urinary Tract Infection

UU – Ulster University

WISH - World Innovation Summit for Health

Note on Access to Contents

Chapter 1 – Introduction

1.1 Introduction

Healthcare provision is under pressure to provide high quality care at a time when people are living longer with growing care requirements from an ageing population (Dannapfel et al., 2014). The increases in health expectation, low patient adherence to treatment, escalation in adverse medical events and high levels of political interest are in an environment of rising costs (Moraros et al., 2015). The cost inflation is in a period of severe financial austerity which recognises that healthcare is already absorbing large quantities of the national budgets and must seek to improve efficiency (Reijula et al., 2016). Currie and Finnegan (2011) summarises this by stating that “Healthcare now accounts for the largest portion of public expenditure after social security, with total expenditure now exceeding £100 billion and rising”. Simon Stevens, head of England’s NHS, speaking following the elections in May 2015 stated “we’re going to need more funding year by year” and talked of the need to “stabilise NHS finances” (Neville, 2015) as they manage an ageing population. Over two years later following a change of prime minister, in November 2017, Simon Stevens reiterated the message and reported to the press and health service employees that without an increase in spending, waiting lists were set to rise by 25% to five million (Pym, 2017). The NHS must therefore balance a need to improve for the future and address today’s healthcare challenges (Ham, 2017). Healthcare spending pressure is a global issue and “many countries share an increasing concern that healthcare costs have exploded with no evidence of an equivalent improvement in healthcare” (de Souza, 2009, 125). In this context of rising financial pressure and escalating demand there is a clear need to explore operational approaches and innovations that can address operational efficiencies at a scales suitable for the health service productivity challenges (Ham, 2016).

1.2 Lean in Healthcare

These challenges in healthcare and in other public services in the UK necessitate improved management practices in delivering services (Tortorella et al., 2017). Lean is a recognised operational improvement approach used initially in the car manufacturing industries before being adopted by other manufacturing industries, services, government and healthcare organisations (Samuel et al., 2015). Samuel et al. (2015, Pg. 1388) states that "Lean has evolved to be one of the best-known, yet fiercely debated, process improvement methodologies".

It has been utilised in hospitals as a continuous improvement approach with implementations including Rapid Improvement Events (RIE) or "Kaizen" events which gather staff and resources to focus on specific challenge in care delivery through a series of workshops with an output of a new operational approach with measureable outcomes (Stelson et al., 2017). The use of Lean is not limited to RIE events and initiatives such as the "Productive Ward" series have been deployed in the NHS by focusing on quality and utilising Lean principles but rather than creating solutions for one location they have sought to disseminate this approach across hospitals (BMC, 2017). The reported results of Lean implementation include; reduced waiting times, reduced cost, reduced length of stay and increased capacity (Costa and Filho, 2016). Beyond the advocates of Lean there are significant critics with Moraros et al. (2016) highlighting the lack of peer reviewed evidence of improvement.

1.3 Technology in Healthcare

Unrelated to Lean improvements, technology has been developing to meet clinical and cost advantages and this is being adopted into healthcare to meet demands of commissioners, patients and clinicians (Campbell et al. 2017). New technology developments have led to interactions with computers through voice, movement, touch and with the aid of devices to support virtual reality, augmented reality and devices which are worn (Hassan and Yu, 2017). The technology has far reaching impact in an "interconnected world" which is impacting citizen's lives, homes and cities through interaction and automation (Nguyen and Simkin, 2017). Emerging technology categories such as Internet of Things (IoT) and data technology provides opportunities for remote monitoring, machine learning use of sensors, real time feedback, faster processing, sending data and mining data for actionable patterns (Nguyen et al., 2017). Within these emerging and current products, technology has the potential to improve service delivery in healthcare. Nguyen and Simkin (2017), highlight that many of the applications for the emerging technologies are still to be discovered. The adoption of healthcare technology has been "underpinned by the drive to improve the safety, quality, and efficiency of care" (Cresswell et al., 2016). This emergent technology provides examples where healthcare needs have been met by technology and where there is opportunity to address both current unmet needs and emergent healthcare needs in medical technology, diagnostics and other medical uses (Campbell et al. 2017)

1.4 Lean technology in healthcare and the overall Aims and Objective of the Thesis

Diseases that would previously have been fatal are being managed as long term conditions and the English Department of Health (2012) reported that 15 million people in England have a long-term condition. Rising cost per activity and an ageing population with long-term conditions is resulting in healthcare demand that is outstripping the supply of care provision (Porter, 2016). This is an unsustainable position requires a new framework to guide healthcare decision makers. Lean as an operational improvement approach could contribute to a new framework for guiding decisions (de Souza, 2009) however further analysis of this is required to understand the criticisms that are emerging in literature reviews (Moraros et al., 2016). Technology has potential to contribute to the framework but critical analysis of the role for technology in developing Lean in healthcare is required. This thesis will therefore seek to provide a critical analysis of operational improvement insight from Lean and potential improvement opportunities for emerging technologies in healthcare. This analysis will reveal the strengths and gaps in knowledge which will create a theoretical model for the application of healthcare technology which utilises Lean operational improvement insight. The key thrust of the exploration will focus on discovering if Lean approaches and healthcare technology, uniquely or jointly, provide opportunities to identify non-value add activities within the healthcare system and address the demand pressures for healthcare decision makers.

Therefore, the aim of the thesis is;

> *To explore the role of Lean thinking in integrated healthcare patient pathway reform to identify opportunities for improved healthcare technology.*

The research will utilise data associated to healthcare provision to create a longitudinal data set to assist with action learning around Lean reviews of patient flows to assess technology adoption opportunities.

The thesis objectives are as follows:

- Objective 1 – To perform a critical analysis of Lean related theory in healthcare reform and the use of technology within healthcare reform
- Objective 2 – To develop an initial theoretical framework to guide empirical analysis
- Objective 3 – To investigate use of emerging technology to address improvement areas identified.

- Objective 4 – Explore the development of theoretical framework for Lean healthcare technology models which utilises the learning and approaches of Lean and opportunities presented by technology.

1.5 Outline of the Thesis Chapters

This thesis will focus on the use of Lean within a context of continuous improvement in healthcare. The report is broken into a further nine chapters followed by appendices.

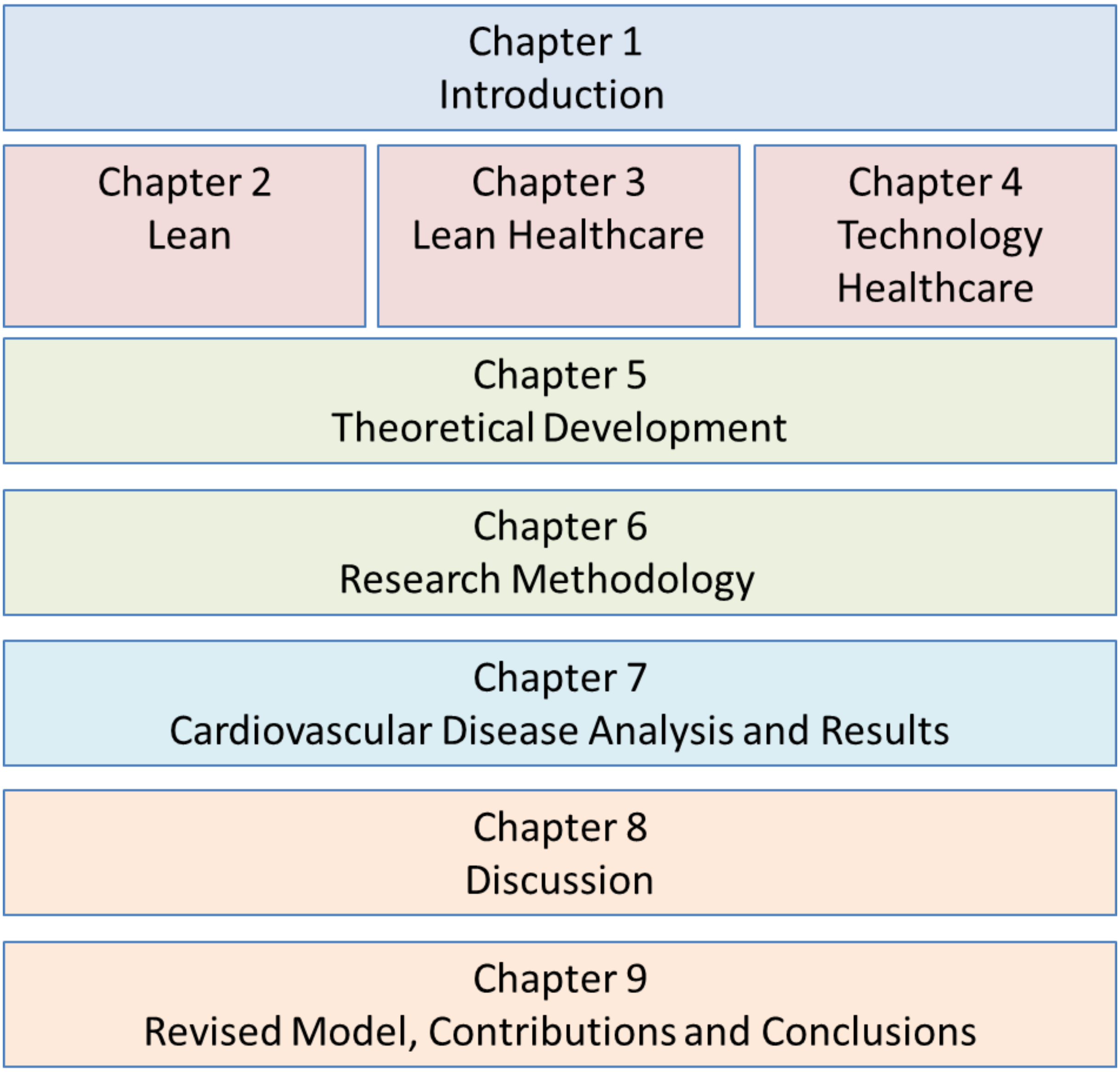


Figure 1.1 – Thesis Outline

- **Chapter 2** will provide an introduction to Lean and a critical literature review of the application of Lean in public services. This critical analysis establishes a context to understand how a manufacturing based approach has been adopted in public services.
- **Chapter 3** will focus on healthcare and provide a critique of literature surrounding Lean in healthcare. This chapter will identify approaches, methods, tools and lessons learned.
- **Chapter 4** will focus on critiquing the use of technology in healthcare. The chapter will build on chapter 3 exploring the role of technology in healthcare reform and its impact on patient value and non-value add activities.
- **Chapter 5** will focus on the development of a theoretical framework and identifying the research questions emerging following the literature critique.
- **Chapter 6** will provide a discussion on the research methodology used and the rationale for adopting it.
- **Chapter 7** provides research results of cardiovascular disease within Northern Ireland as an exploratory case study of the application of Lean and technology to long-term conditions.
- **Chapter 8** provides a discussion of the emerging knowledge contributions from the thesis literature and research which are relevant to Lean and technology in healthcare.
- **Chapter 9** presents a revised conceptual framework which shows knowledge contribution, conclusions and recommendations for further research.
- **References**
- **Appendices -** Provide an overview of qualitative analysis, meetings, publications and conference related to the thesis outcomes and the author.

Chapter 2 - Literature Review of Lean and the Application to Public Services

2.1 Introduction

The aim of this thesis is to explore the role of Lean thinking in integrated healthcare patient pathway reform and to identify opportunities for improved healthcare technology. To understand how Lean continuous improvement approaches were adopted by healthcare it is important to first review the principles of Lean and the historical context. This chapter presents these origins of the Lean principles and provides the link between its historical context in the manufacturing industry and the transfer to public services of Lean. The application of Lean outside of manufacturing has been challenging and applying Lean thinking to other sectors has required an ability to "evolve" Lean thinking and "localise" the learnings. (Hines et al., 2004). An overview of this chapter is available in figure 2.1.

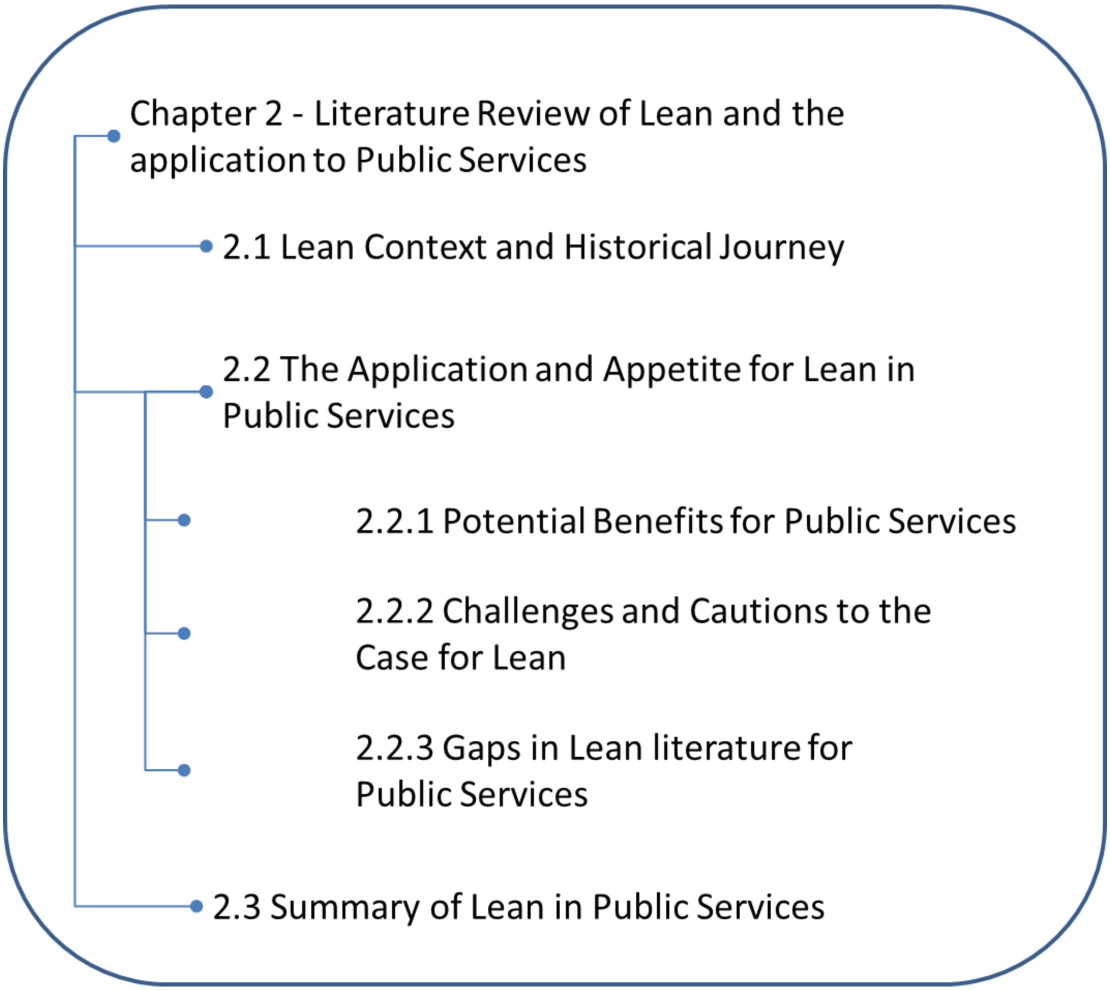


Figure 2.1 – Chapter 2 Overview

2.2 Lean Context and Historical Journey

To understand how Lean thinking applies to healthcare it is important to firstly understand the origins of Lean (Samuel et al., 2015), how it transferred to the public sector including health (Radnor, 2009) and if Lean based improvement initiatives can assist in addressing the budget shortfalls of public sector organisations (Antony et al., 2017). Lean is primarily linked back to the Toyota motor company who developed a Toyota Production Systems to create a competitive business model at a time when cash flow was restricted and they were competing against cash rich mass production companies such as Ford (Womack et al., 1991). The creation of the Toyota Production system emerged from a need to increase efficiency by removing waste from the system. The Japanese manufacturers had to learn to build each product according to individual needs and move away from mass production practiced by American manufacturers such as Ford in the post war era. (Ohno, 1988). Lean's origins can be found in these early Toyota production system and linked to the leadership of Taiichi Ohno in the 50's, 60's and 70's (Hines et al., 2004) Samuel et al. (2015) notes that the term Lean was initially used by Krafcik (1988) to compare western approaches to the less resource intensive "Lean" Toyota production systems but was made popular by Womack's management book "the machine that changed the world" Womack et al., 1991). The Lean way of thinking explored in the book provided a high focus on quality, employee engagement, value creation in each activity and the removal of wasteful activities within a continuous improvement culture. The continuous improvement culture provides short term quality improvements and efficiencies with longer term system wide improvements. (Hung et al., 2017). The approach has a heavy focus on quality and flow which was counter to the mass manufacturing and batch processing evident in the production environments at the time of writing the book (Womack et al., 1991). The translation from the original Toyota Manufacturing System to the Lean practices evident today has not been without issue as a misunderstanding of the meaning of the Toyota Production System can lead to a tools based approach rather than understanding the culture and approach that it requires for success (Liker and Rother, 2011, pg. 1). This failure is not limited to the other companies as Liker and Convis (2011) note that even Toyota had to be reminded of this return to basics when quality production failures emerged in the last decade.

This continuous improvement approach was outlined in the early seminal work of Womack, Jones and Roo's in their work "The machine that changed the world: The story of Lean production." (Womack et al., 1991). It draws out a number of case studies and examples in the manufacturing industries highlighting what they refer to as a "Lean" approach. The ideas from this were developed further, structured and presented in the "Lean Thinking" book by Womack and Jones in 1996 and updated in 2010 (Womack 2010). Lean has had many critical reviews over time with a body of academic literature critiquing its style, evidence, staff impact, suitability for transfer and financial benefits (Samuel et al.,2015). Based on this critique Samuel et al. (2015) concludes that Lean has impacted on many aspects of "everyday life", education, healthcare and manufacturing. From the seminal work the authors presented the 5 lean principles which are outlined in various forms across most Lean literature. Miller (2015) records these five principles as;

- Identification of customer value;
- Management of the value stream;
- Developing a flow production;
- Using pull techniques; and
- Striving to perfection.

The principles are the foundation of Lean continuous improvements, including healthcare, despite challenges about being developed around a Japanese culture and the car manufacturing industry (Bowerman and Fillingham, 2007). The early work focused primarily on the manufacturing industries; however it made a number of attempts to consider the application of the principles to other areas such as medical care (Womack, 2010, 289). The authors challenge the healthcare professionals about "entering a world of queues and disjointed processes" and blaming the providers on viewing the provision of care from the "standpoint of organisation charts, functional expertise and "efficiency". The criticism reflects the core argument of the Toyota Production System where traditional business owners were more concerned about keeping the machines moving than on producing a quality outcome (Womack et al., 1991). The publications exploration of "waste" features in a large number of Lean transformation approaches such as the "Unipart way", which was used in the first applications to public services (Radnor 2013). Waste in the Lean context means activities which add no value from the perception of the customer and can be an output of "Value Stream Mapping" which looks at processes from the start to the finish (Tortorella et al.,2017). A crucial element of Lean is not just to understand the process but to remove these wastes. Recent articles highlight the continued use of the Lean five principles as a means of identifying waste and highlight processes such as arrival and scheduling as creating wastes in healthcare Miller (2015). Nordin (2017) also highlights that the adoption of Lean is not a guaranteed success as many manufacturers have failed where they did not consider reshaping the purpose, system and work culture.

In summary, the use of the Toyota Production System, which was later labelled as Lean, was a success in providing high quality cars at lower costs (Samuel et al., 2015). The use of Lean in UK public services reflected a desire from the public services to implement business process improvement techniques to increase efficiencies (Radnor, 2009). The promise of high quality delivery for less cost and resources appealed to public services budget holders under pressure to provide outputs with less money and to avoid alienating staff (Radnor and Walley 2008). Lean continues to have many challenges for adoption in the public services with benefits and evidence not fully established (Antony et al., 2016) and a number of critics have challenged the sustainability of improvements (McCann, 2015). The use of Lean come with some caution about adopting the approach properly and criticism that "Lean can be described as polymorphic; meaning different things to different people" (Samuel et al., 2015, 1388). Lean has been accused of focusing on tools and quick wins and a more holistic approach is needed (Antony et al, 2016). Despite the criticism and the lack of clarity on its definition it has had a clear influence as a management improvement approach (Samuel et al., 2015). This influence and impact has included the public services which will be discussed further in the next section.

2.3 The Application and Appetite for Lean in Public Services

As the purpose of this thesis is to understand Lean healthcare it is important to understand the bridge from the manufacturing industries to public service which then became adopted in healthcare (Radnor 2009). Lean was initially applied to process oriented elements of the public services such as HMRC before being deployed in healthcare sites (Radnor 2009). This reflects an observation from that there is a historical trend of transferring management philosophies from large companies to government with examples including Business Process Reengineering and Total Quality Management (Moffett, 2015). Leseure (2010) documents the early Lean transfer to UK government through the application of an approached branded as the "Unipart way" which was applied to the HMRC's exploratory projects which were referred to as "Pathfinders". The application of Lean in public services should not be assumed to have been a predetermined outcome as there are context considerations that challenge its application such as the lack of process consistency in public services (Radnor and Walley, 2008). The key issue is that Lean tools and techniques requires underlying process understanding and linkage to strategy that may not be there in public services and could create instability as the improvements have no sustainable platform (Radnor and Walley, 2008). Despite the criticisms outlined in the previous section, the combination of high quality, high output and lower cost of Lean was however attractive to public services due to the emphasis on front line staff engagement and a political and managerial desire to show evidence of improvement (Radnor 2009). While recognising the critiques of Lean, it has been a significant influence on public services such as Health and Education (Samuel et al., 2015). The Operational Efficiency Programme, Treasury (2009, 83) documents how tools such as Lean can "harness staff insight and expertise and identify the redundant or avoidable steps…" leading to more efficient service". The participative nature of Lean has an attraction to the public services as a means of improvement and to address the potential resistance to change (Radnor, 2010). One of the recommendations from the report (Treasury 2009) is the need to "use continuous improvement tools such as Lean more systematically across the public services, and develop capacity to examine themes that cut across organisational boundaries", moreover suggesting that public service improvements are interested in Lean as a proven route to improvement. This has manifest itself in the years after this report with the English Police service using Lean as an improvement approach to address budget pressures (Barton and Mathews, 2017). Radnor's (2008) article reiterates this appetite for public service improvement and the interest in Lean as a potential route to improvement. Her research quotes examples of interest in public services organisations who have applied Lean approaches, including healthcare, government agencies, local authorities and an RAF base. More recent literature critiquing the application of Lean in public services includes; education (Antony, 2015), police (Barton and Mathews, 2017), health (McCann, 2015), public road works (Aziz et al., 2017).

The interest in Lean compared to other approaches was underlined in the Institute of Management review of business process improvement methodologies in the public services (Radnor, 2010). Other approaches included Six Sigma, Lean Six Sigma, Business Process Reengineering (BPR), Total Quality Management (TQM) and European Foundation Quality Management (EFQM) (Radnor, 2010). The review recognised that there are a number of improvement approaches being used across the public services but of the 165 sources of improvement initiatives identified the majority, 51%, focused on Lean. More recent literature describes how Lean has been deployed widely in a “fragmented” manner but with evidence of some successful application (Antony et al., 2016). Radnor (2008) explores the application of Lean in public services and the potential conflict with the culture. She emphasises the need to adapt to the context of the public services but not to use this as “an excuse for avoiding manufacturing methodologies as a means of efficiency gain”. Antony et al. (2016) support a similar position by stating that there needs to be a better evidence base and more holistic approaches.

To explore this further this section will critique literature under the following topics;

- Potential benefits for public services
- Challenges and cautions to the case for Lean
- Gaps in Lean literature for public services
- Summary of Lean in public services

2.3.1 Potential Benefits for Public Services

The purpose of this thesis is to explore literature in healthcare. By understanding the benefits of developing and applying Lean in public services one can begin to appreciate the opportunity for healthcare. The literature emphasises the challenge of adapting Lean to the public services (Radnor 2008) and tangible benefits emerging from the application of Lean such as reduction in waste and lead times (Tortorella et al, 2017). Radnor’s (2008) reports on a diverse set of improvement activities across the public services with activities providing positive outcomes such as productivity increases, cost reductions, faster turnaround times, improved customer satisfaction and decreased staff turnover. An Institute of Management review of business process improvement methodologies in the Public services (Radnor 2010) supports this view that Lean implementations have a strong evidence base of providing significant improvements. The “Operational Efficiency Programme: Final report”, Treasury (2009), makes reference to Lean initiatives in the Department of Work and Pensions in a programme called the “Lean Way”. The report highlights savings, at the time, of approximately £10M. Further improvements were documented with other references to initiatives, such as the Job Centre Plus, with efficiency, quality and staff satisfaction. The literature has not been consistent about all these positive aspects but Samuel et al.(2015) analysis show the movement of Lean from manufacturing to public services as having a significant impact and maintaining the interest of both academic and service improvement organisations.

A gap not addressed in literature is the lack of progress. Samuel et al. (2015) highlights 25 years of Lean literature as a success yet the same wastes and issues are present in each academic review without a significant step forward. The wastes reported in Tortorella et al, in 2017 are the same wastes reported in public sector studies by Radnor (2008) which will map back to Womack (1991). The gap that is emerging is where there is recognised benefit which is not evolving to become larger benefits or where there are failures these are not becoming systematic lessons learned which should not be repeated. The failures of the past are repeating themselves and Lean is not codifying the lessons learned.

In summary, one can see a strong evidence base of appetite and application in the public sector. A literature gap is emerging where Lean is identifying wastes which were evident back in 2008 literature (Radnor, 2008) and these where recognised by the public sector (Treasury, 2009). The development of Lean in public services beyond these early findings is somewhat static with more recent literature in Higher Education (Antony, 2015), Policing (Barton et al., 2017) and Health (Cheng et al, 2015) showing the repetition of the experience of the early adoption of Lean in public services. In literature where there are improvements there are also challenges identified that will be considered in the next section.

2.3.2 Challenges to the Case for Lean in Public Services

Despite positive reviews of Lean, “many criticisms” have been made of various aspects of Lean (Samuel et al., 2015). In addition to the criticism, various challenges have been identified which provide lessons learned in public services that could be applied to healthcare (Radnor 2013). Two areas emerge from literature critiques. One is about Lean deployment and one being about the public services readiness for Lean.

The criticism and challenges of Lean deployment include a lack consistent definition and purpose with no shared understanding of what is meant by Lean (Samuel et al., 2015). Samuel’s critique of 25 years of Lean since the publication of “The machine that changed the world” highlighted that Lean has evolved over time without clear definitions. A Lean deployment may focus on tools such as value stream mapping (Aziz et al., 2017) while another deployment may seek other goals around leadership, quality or staff engagement (Antony 2015). The outcomes, such as cost reduction in a period of austerity, may be the prime driver (Smith, 2016) which removes any longer term vision and ultimately leads to “eroded” improvements and Lean being referred to as a management “fad”. The lack of definition creates challenges and criticism which if addressed alongside better evidence could demonstrate a more acceptable adoption (Antony, 2016). Secondly, a lack of focus on the customer has also been highlighted by Radnor (2013) where she stated that Lean will fail unless there is a clearer focus on the customer (or client) value. This lack of focus on the customer is reflected in academic literature where the focus was on tools (Linskog, 2017), budget pressures (Barton 2017) or staff (Eriksson, 2017). Radnor (2008b) highlighted these as including a lack of clarity on who the customer is the presence of functional silos and a lack of system or joined up thinking beyond one's own function. Radnor (2013) report on the failure of Lean in the public services and identifies "a lack of understanding of the centrality of the customer," as being a key challenge. The potential barriers of not achieving buy-in from staff were highlighted by Radnor (2008a) and if this is taken in the context of needing front line engagement (Treasury 2009) then potentially there is a fundamental failure.

Similarly, Lean implementations identified a number of barriers linked to the nature of public services as a result of its approach which challenged the successful application to public service. The challenges include a lack of basic process knowledge by public service providers and availability of process data that would be expected in manufacturing environments (Radnor, 2008b). This highlighted a failing in the organisations to understand their current processes and data which was also part of the critique of Lean for higher education (Antony, 2015) where collecting data of relevance was identified as a challenge. The application of approaches such as Lean in an immature process which lacked relevant data is somewhat risky as Lean will initially destabilise an unstable environment (Radnor 2013). In addition, the implementation of the Lean approach also revealed a capability gap in the area of change management. The 2009 "Operational Efficiency Programmes Final report" (Radnor 2010) highlighted the need not only to deliver improvement programmes but also to build the capacity and capability within the system to introduce and manage continuous improvement. This reflects Radnor (2013) comments that Lean implementations placed too much emphasis on workshops and tools. A fuller more complete view of the organisations is needed at an "agency level" beyond the specific interventions to address the challenges of Lean in public services (Antony et al., 2016). Continuous improvement is a fundamental element of Lean beyond the tools and workshops and was unfamiliar to many public service organisations. The point of capacity building is often missed in academic articles which are reviewing the success or otherwise of an initiative as it highlights “short sighted” objectives at point in time rather than a development of “genuine improvements” and a capability to continue improving (Smith, 2016). Similar to the Operational Efficiency, the review of business process improvement methodologies in the public services (Radnor 2010) reported the need for capability and capacity building. There is a need for strong and committed leadership or improvement infrastructure and the programmes to build a strong capability base to manage change Radnor (2008b). The Radnor (2010) review went further and provided a criticism of some of the organisations not adopting the true philosophy of continuous improvement. The use of a “House of Lean” diagram (below) attempted to introduce the concept of a more holistic approach to continuous improvement. This attempts to move the organisations away from short sighted improvements towards a scientific management continuous improvement approach. A criticism is that the absence of this continuous improvement capability means that improvements are “Championed”, “diluted” and “eroded” McCann (2015).

In addition to the Lean challenges that are emerging from the analysis of the Lean literature one area that is not addressed in the public services literature is the role of government. What was clear in the 2007-2010 literature and historical journey was that government politics was putting the civil service under pressure to increase efficiencies. At this time the UK government were spending heavily under a Labour government but needed to show evidence of improvement (Radnor 2007). With the 2007 credit crisis beginning to make an impact on the decision making of the country in 2010 the government switched to a conservative coalition, with the Liberal democrats, and an austerity agenda. Lean literature does not explore this linkage between government policy and the success of Lean despite evidence of it impacting front line services. Literature, such as Smith (2016), make reference to services dealing with cuts in budgets and Antony (2016) make reference to efficient and effective public services being the context of their work. What is not clear is the linkage between an austerity agenda of the last seven years versus a more prosperous government environment in creating a culture of continuous improvement.

In summary, there are number of key challenges to introducing Lean in the public services both in Lean application and also in the manner in which public services prepare for, and adopt, Lean. Many of these challenges apply to healthcare and will be explored further in the chapter on Lean healthcare. Within the public services Lean literature, a number of gaps or criticisms has been identified and are listed in Figure 2.2.

Summary Points

Challenges

- Translating the Japanese Car manufacture Style and language to civil servants (Samuel et Al.,2013).
- Lack of Consistent Definition for Deployment (Samuel's, 2013).
- Lack of Customer Focus (Radnor, 2013).
- Lack of process knowledge in public services (Antony, 2015).
- Functional Silos Preventing Customer Value Being Achieved (Radnor 2008b).
- Short sighted nature of deployments lacks continuous improvement (McCann, 2015).
- Lack of Staff buy in (Treasury, 2009).
- Lack of Capability Building for Continuous Improvement (Smith, 2016).

Figure 2.2 –Key Challenges to Lean in Public Services

2.3.3 Gaps in Lean literature for Public Services

When investigating the literature one must recognise that the implementations were being completed at a time of rising technology investments in UK public services. UK public services spending on science and technology rose from £1.4bn in 2000/01 to £4.8bn 2015/16 (Statistica, 2017). Despite the level of investment, there is a paucity of Lean literature on its potential. Authors such as Radnor (2008a) do not draw out the potential that technology could provide in addressing the gaps, establishing a baseline process data, building capacity or converting short term wins gained into longer term business as usual.

Gaps additionally appear in identifying the purpose of the system in public services (Seddon, 2005). Seddon draws on the titles of previous books on “Freedom From Command & Control” (Seddon 2003) and “Systems Thinking in the Public Sector” (Seddon 2005) and reveals a number of insights in the area of public services reform that are often absent from the Lean reviews and terminology (Seddon 2008). He challenges the concepts of “command and control” reforms and the target culture that is dominant in public services. By doing this, the purpose of the system is being missed and the performance targets are creating false drivers for managers which don’t align with customer value. Gubb (2009) goes further by highlighting that Lean can expose “the fallacy of targets” and the need to look at the system as a whole. He overlays this point by emphasising that staff can become obsessed with data about targets instead of data about the demand from consumers. Seddon’s (2008) overarching theme is about understanding the purpose of the system from this perspective one can build processes and systems, which use real data, which the organisation can utilise to improve. He introduces a concept of failure demand which is “demand caused by a failure to do something or do something right for the customer”, essentially demand created due to a failure elsewhere in the system. Antony (2016) makes some attempt to address purpose of the system in his finding by suggesting a more “holistic approaches” to delivering value.

Similarly McGrath (2015) makes reference to “cross-boundary conflict” to initiate governance at a higher level in the system. In both cases these were recommendations rather than observed in Lean deployments and lacked the direct linkage to value for a citizen or removing wastes in the system which Seddon (2005) had identified. The concepts of “failure demand” which is largely missing from Lean, but relevant to public services, are explored later in reference to Lean and healthcare demand.

In summary, within the public services literature for Lean there is absence of technology discussion and the value it could bring to addressing value for the citizens and addressing waste within the service provision. This lack of technology consideration is at odds with the increasing levels of technology investments within public services. Additionally the challenge of system thinking for customers is not addressed in Lean literature despite work in public sector reform revealing issues such as failure demand which is linked to not delivering value for the citizen. There is therefore a gap in Lean system thinking which crosses silos of service provision to address failure demand and improve value for the customer. Finally, there is a general lack of quality literature which evidences the benefits of Lean (Antony 2016) despite Lean “rapidly diffusing” in public services (McCann and Hazzard, 2015).

2.4 Summary of Lean in Public Services

As the purpose of the thesis is to explore the role of Lean thinking in healthcare and identify opportunities for improved healthcare technology one can draw a number of conclusions from this chapter on public services. Firstly the Lean principles have a strong application outside of car manufacture with significant evidence of an appetitive to deploy Lean (Radnor 2009). This has led to encouraging outcomes for those who have adopted this approach (Samuel et al, 2015). The approach is particularly appealing due to harnessing knowledge of existing staff through the approach (Eriksson, 2017). Secondly the Lean approach exposes a number of gaps in process understanding, data maturity and understanding who the customer is (Radnor, 2013). These are negative in terms of speed of deployment but positive in terms of introducing an approach to identify weakness. Furthermore, gaps within this are the ability to support continuous improvement rather than a short term improvement which will diminish rapidly with time (McCann, 2015). Part of this longer term improvement will require an ability to identify the relevant capabilities, including leadership, to move beyond basic rapid improvement events towards a Lean philosophy (Antony, 2015). This need to build improvement capacity is reiterated as a threat of failure if not addressed (Radnor, 2013). Finally there are gaps in Lean literature which are shown in table 2.3. These include a lack of development of the Lean approach beyond repeating the approach shown in Lean literature in 2008 - 2010 in more locations and geographies around the world (Costa et al., 2016). This gap fails to address some of the challenges emerging in any meaningful way. Similarly a gap emerges around the lack of addressing the role of technology in Lean literature which does not align with a growing trend for the public sectors increasing investment in technology (Statista, 2017). This will be explored further in this thesis due to its paucity in the review of the Lean literature. System thinking which crosses functional silos to address real demand from customers rather than artificial targets (Gubb, 2009) will also be explored in more depth in this thesis as Lean should reflect customer value and not focus on providers value as this can create failure demand (Seddon, 2005) The next section will move from a general public service focus to specifically assess the impact of Lean within the context of healthcare. Figure 2.3 provides a summary of the key challenges and gaps to Lean in public services

Summary Points

Challenges

- Translating the Japanese Car manufacture Style and language to civil servants (Samuel et Al.,2013).
- Lack of Consistent Definition for Deployment (Samuel's, 2013).
- Lack of Customer Focus (Radnor, 2013).
- Lack of process knowledge in public services (Antony, 2015).
- Functional Silos Preventing Customer Value Being Achieved (Radnor 2008b).
- Short sighted nature of deployments lacks continuous improvement (McCann, 2015).
- Lack of Staff buy in (Treasury, 2009).
- Lack of Capability Building for Continuous Improvement (Smith, 2016).

Literature Gaps

- Lack of development of Lean beyond 2008-2010 Literature – repetition and geographical extension (Costa et al., 2016)
- Understanding the impact of Government policy – do austerity political decisions impact Lean? (Smith, 2016)
- Lack of Lean deployment consideration of technology to address gaps, establishing a baseline process data, building capacity or converting short term wins gained into longer term business as usual (Ker et al., 2014).
- Lack of system thinking in Lean deployments – Lean functional silos being created in public service which don't address customer value and don't address failure demand (Seddon, 2005).
- Lack of quality literature which evidences the benefits of Lean (Antony, 2016)

Figure 2.3 –Key Challenges and Gaps to Lean in Public Services

Chapter 3 - Lean in Healthcare

3.1 Introduction

The overall aim of the thesis is to explore the role of Lean thinking in healthcare and to identify opportunities for healthcare technology. The previous chapter highlighted that the Institute of Management review of business process improvement methodologies in public services (Radnor 2010) detailing that of the 165 sources of public service improvement initiatives identified, 51% of them focused on Lean. The largest proportion of these, making up 35% of the total, applied to healthcare. Healthcare has been of interest to Lean experts with one of the key influencers in Lean, Jones (2006), highlighting the comparison between the early Toyota model and the NHS by drawing on the need to engage staff to make improvements. Lean continues to be a key operational improvement tool in healthcare with recent Lean examples including implementations to address patient safety issues (Cheng et al., 2015), address quality issues (White et al.,2017), improving medication dispensing (Jung-Ing et al., 2014), improve laboratory services (Hayes et al, 2014) and to increase efficiency (Patton et al., 2015).

This section will analyse the literature addressing Lean in healthcare to identify the successes and criticisms. This will cover the following four areas;

- Critique of Lean in healthcare
- The appeal of Lean to healthcare
- Challenges in adopting Lean healthcare
- Summarise the learning and emerging gaps in the literature

An overview of this chapter is available in the following figure.

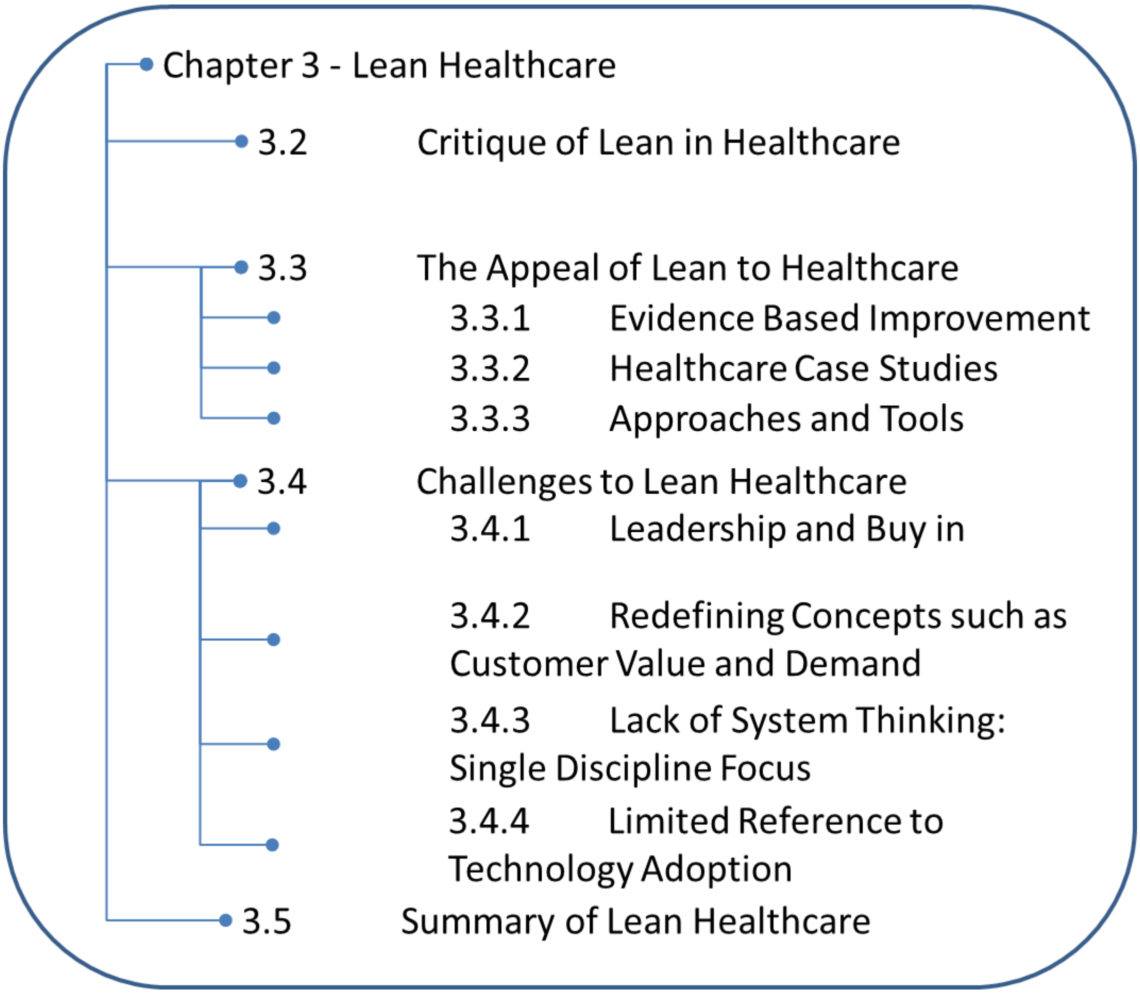


Figure 3.1 – Chapter 3 Overview

3.2 Critique of Lean in Healthcare

A number of systematic reviews of Lean in healthcare will be critiqued in addition to specific academic case studies. From this literature review key tools and techniques across the Lean literature will be derived to identify patterns and approaches which will progress the understanding of Lean in healthcare. This literature based critique assists in addressing the aim of the thesis by identifying opportunities for improved healthcare technologies for integrated healthcare patients. This section will identify the key points emerging in the literature critique before progressing to the appeal of Lean and Challenges in sections 3.2 and 3.3. The key points emerging to be reviewed in this section include;

- Purpose of Lean in Healthcare
- Definition of Lean in Healthcare
- Leadership and Staff Engagement
- Addressing Quality in Healthcare
- Provider Focus, not Patient
- Lack of Clarity on the Lean Customer
- Defining Value

De Souza (2009) provides a heavily cited systematic review article identifying key Lean literature and outlines a useful perspective on the application of Lean in healthcare in the UK pointing to NHS Modernisation agency work, in 2001, being the first appearance of Lean in UK Healthcare. Lean healthcare deployments are recorded across the world including small deployments through to large scale deployments impacting 6 million participants (Moraros et al., 2016). De Souza (2009) summarise the context in which Lean is applied to healthcare to address concerns shared by many countries of rising healthcare demand, rising healthcare costs and no related improvement in care. Lean was introduced to healthcare to address productivity issues linked to cost (Cheng et al., 2015) and also to address quality issues (White et al., 2017). Within Lean implementations there is a tension in understanding if health quality outcomes or process productivity are the key output. The mortality or morbidity of a patient is an important but equally the financial status of a healthcare organisation is also important for sustainability despite being seen as secondary (Jorma et al., 2016). De Souza (2009) although over seven years old, the article provides a seminal relevant piece of critique of Lean in Healthcare highlighting the context of healthcare needing to do more with less. This realisation of his prediction is articulated in the current NHS England strategy document “Five Years Forward” (NHS 2014) which addresses budget deficits within England. Additionally de Souza (2009, 126) highlights the challenges of providing new capacity without adding cost, quoting Silvester (2004), as challenging NHS beliefs on capacity by saying:

> "They argue that "it is possible to eradicate queues in the NHS" without using the "failed approach of continually adding capacity".

de Souza (2009) picks up on points from Womack (1996) about decreasing the average length of stay by 50% in hospitals to increase capacity. Pointing to the early NHS Modernisation Agency (2001) as being one of the early healthcare adopters of Lean in healthcare, he then goes on to highlight improvements in patient flow, process step reductions and providing balanced scorecard approaches. Silvester (2004) also reviews a waiting list reform focus. From this critique of Lean healthcare literature one can see common purposes for Lean implementations being linked to cost control, productivity, quality and patient improvements. This is repeated across in Lean healthcare literature from different use cases within healthcare which each linking to quality, cost and productivity. For example Cheng et al.(2015) focusing on productivity and quality linked to referral information, Patton et al. (2015) focused on lower cost and resource utilisation linked to Chronic coughs and Gavriloff et al. (2017) focused on higher throughput though better use of scheduling in medicine. A critical aspect of this however is that although there are common purposes one aspect of the purpose, such as reducing errors, may dominate a deployment and cause conflict with the overarching purpose of providing high quality at a lower cost.

While the purposes of Lean within Healthcare have some degree of clarity, the definition of Lean is less clear. One can see an umbrella of Lean activities reflecting a diversity of approaches or alternatively Lean has a lack of a "formal definition" (Samuel et al., 2015). Young and McClean (2007) describe Lean implementations as a pragmatic practice rather than pure. Lean activities have focused on reducing mortality, reducing infection, reducing length of stay, reduced waiting times, reducing missed appointments, improving team work and reducing waits (Moraros et al., 2015). These focus areas and others may have utilised a Lean title on an improvement initiative but this may only reflect utilising one or two Lean principles or tools without any intention of a wider scale Lean implementation (de Souza, 2009). This can be viewed as Lean being a broad approach or alternatively there is a criticism that Lean is not a standard approach allowing comparisons between implementations. This lack of definition influences critiquing Leans effectiveness which is reflected in Moranos (2016) systematic literature review of Lean interventions with the key question of "do they actually work". The conclusion of the systematic review was that from the studies they analysed the interventions had negative impact on financial impact and worker satisfaction, no statistically relevant link to patient satisfaction and inconsistent benefits on process outcomes. The report however is at odds with other published work and fails to sufficiently draw out what do they mean by Lean. What has been referred to as Lean is inconsistently deployed approaches across the healthcare providers. There is no standard Lean implementation as care providers target various tools or outcomes for their own purposes rather than an aspiration to have a Lean implementation. This reflects the previous point linked to Silvester (2004) where there was a description of Lean being a broad umbrella of activities rather than a single approach. Secondly the Moranos (2016) study had filtered out a high proportion of the unique articles with only 22 out of 892 articles covered. This leads more to question about if there is a lack of quality literature and studies rather than an assessment of the impact of Lean implementations. What is unclear in the literature is if this is a lack of effectiveness or a lack of evidence of effectiveness which is picked up as a tension between the practitioner and the academic communities (Samuel et al., 2015). What is clearly emerging in the critique of the literature is lack of definition of Lean and a need for more evidence to justify the return on Investment (Antony et al., 2016).

Burgess and Radnor (2012) draws out some key points on staff and leadership within their research on service improvements within the English NHS which provides a critique of the Lean implementations across three hospital trusts case studies in England. The article compares two hospital trusts seeking a foundation trust status which would allow more autonomy and a hospital trust that has already achieved that foundation trust status. Reporting that despite difficulties of leadership, discussed later, all the implementations had evidence of improvement. This points to somewhat of a conflict for Lean in that there is a key assumption that Lean will need clear leadership when in reality healthcare leadership is in flux. Senior management commitment and organisational culture are seen to have a potential impact on outcomes (Chiarini et al.,2016); however it is recognised that staff are operating in a chaotic situation with frequent structural changes to leadership (Serr Roszell, 2014). Similarly the organisation culture of decision making centralised with doctors and a lack of teamwork or decentralised authority make Lean difficult to implement in healthcare (Drotz and Poksinska, 2014). One can see a tension within the research that there is a best practice need for leadership buy in; however there are improvements and acceptance of Lean despite this lack of stable leadership and organisational stability.

Another key area emerging in the Lean literature critique is in addressing quality to improve patient safety and removing errors (White et al., 2017). Mazzacoto's (2010) identified approximately 1000 Lean healthcare articles and provided a systematic review with 112 of these articles being relevant and 27 containing empirical studies. The research identifies four influences to understand Lean literature which are context, interventions, mechanisms and outcomes. The methods used focused on methods to understand process, promote efficiencies, improve error detection and manage change through a scientific approach. The identification of error detection and failure in the health provision can avoid costs and save lives (Spears, 2005). This is pivotal research in Lean healthcare as Spear (2005) had previously written about decoding the DNA of Lean and this research transfers the lessons learned into healthcare. The article goes further by identifying potential saving of $20-40 billion dollars (Spears, 2005, 81) in USA hospitals if the care providers can eliminate the ambiguity and workaround found in healthcare practice. The linkage between errors and cost is absent in other Lean literature and the concept of the cost of failure is not explored across most of the literature resulting in a choice in a Lean implantation between a quality focus and a cost focus which doesn't align with core Lean principles of poor quality being a waste leading to a cost. There are some different principles to waste in healthcare versus the cost in a car manufacturing line as the cost in healthcare may be about disease complexity, additional procedures or litigation which does not translate from manufacturing. For example Spear (2005) identified costs linked to medication errors, infections and medical errors, and while the medical errors can find parallel application to procedure errors in car manufacture, the medication errors and infection issues are more difficult to find parallels with manufacturing processes. The Spear (2005) report was significant for healthcare as it critiques poor care outcomes in terms of medical error and infections. For example, according to the article, 98,000 people die in US hospitals each year as a result of medical error. It also challenges the notion that costs can't be released from the system at the same time as providing improvements in care. This is reflected in the outcomes measures highlighted in Morraros et al. (2015) where the outcome focused on either "Health Outcome" linked to death or infection or "Process Outcome" such as reduced waiting time or faster procedure. A research gap therefore emerges in the cost of errors and failure and reluctance for both cost and quality to be addressed in the same Lean activity. This gap may be linked to the poor definition of Lean deployments where a deployment only reflects one or two principles or tools being deployed or an underlying reluctance to quantify quality errors costs and to hold on to a belief that healthcare improvements must come at a cost rather than as a route to saving money. In each of these cases the error waste is counter to patient value which emerges in the literature critique of Lean healthcare.

A key literature gap emerging is that Lean in healthcare focuses on the healthcare provider and not the patient. Moraros et al. (2015) systematic review of Lean Healthcare lists the application of Lean to hospitals, intensive care units, emergency departments, operating rooms, clinics and other departments. In chapter 2 of this thesis, the five Lean principles were outlined to reflect the Womack et al. (1991) codifying of the Toyota Production System. Miller (2015) paraphrased the first two principles as 1) Identification of customer value and 2) Management of the value stream. However, when we critically analyse the Lean literature, the Lean value delivery is based on the care provider and no attempt is made to understand the full value stream for the patient. If one looks at the value stream for a patient, the activities that add value will begin before the specific healthcare providers department and end after leaving this department. For example a patient in an operating theatre will have had appointments, reviews, tests and decisions prior to the operating theatre being used and after leaving the theatre they will have post-operative care, discharge and rehabilitative therapy. This means that Lean has been applied to the provider’s value stream and not the patients. The focus is on single hospital wards, operating theatres and activities which fail to consider multiple elements of a patient journey beyond these hospitals (Spear, 2005). Porter’s (2013) challenges healthcare departmental silos and although not specifically badged under a Lean review it uses Lean language and approaches. The article contradicts some of the previous Lean applications as it begins to questions the ability of healthcare in defining proper goals. This is a challenge to the basic foundations of Lean as the primary principle of Lean is to define value for the customer. Porter argues that the wrong goals which support high volumes and related profit are being sought rather than health outcomes.

Linked to the literature gap of Lean being focused on healthcare providers and not the patient is the issue of who is the customer in Lean healthcare implementations. Healthcare RIE events utilise language around the patient being the customer within the boundaries of their clinic or department (Baril et al., 2016). Lean literature however reveals a complex set of relationships with numerous stakeholders such as patients, health plans, employers and suppliers seeking to balance financial performance, patient satisfaction and clinical governance (Dobrzykowski et al., 2016). Porter’s (2013) review however states that the overarching goals should be patient value and health outcomes that matter to the patient. This patient focus is contrary to Lean application in many of the institutions who have attempted to apply Lean for processes outcomes rather than against a patient value concept (Moraros et al., 2015). This is also evident in Lean healthcare literature such as Balle and Regnier, (2007), Bowerman (2007) and Hayes (2014). Young (2008) provides a discussion on the concept of value to a single customer and notes the complexity around this in healthcare. The article does not resolve the tensions about who is the customer in Lean healthcare but summarises customer value as having three dimensions of clinical, operational and experiential. This highlighted Lean in healthcare as having an absence of a single or unique customer. This customer definition can be somewhat problematic due to separations between users, consumers and on occasions the patient being a co-producer of the product. One could argue that an appeal of Lean in healthcare is that even if it is failing to adequately identify the customer (Young 2008) or properly define value (Porter and Lee, 2013) the use of Lean initiates the debate on the concept of the patient being the purpose of the system and moves it away from the clinician being the purpose of the system. In the absence of alternative approaches the approach is appealing, even if not perfect.

Related to the debate on who the Lean customer should be is the question of what is meant by value to the patient as the customer? This real patient value Porter and Lee (2013) states is not measured in current Lean or healthcare delivery as although outcomes about survival are measured other patient quality measures are not. For example in the case of prostate cancer this may include other outcomes such as incontinence and decreased sexual function which are not routinely measured and may even lead to different clinical interventions if they were measured. Other diseases will have similar patient health outcomes around mobility, pain, ability to return to work, anxiety, speed of recovery and sustainability of health and function. Attempts have been made to focus on patient value in initiatives such as the “productive ward” series in the NHS which have used language around releasing “time to care” by improving quality and delivery of care however it is unclear if they result in better patient value delivery or if it is just more engaged or productivity staff within the organisation metrics (White et al., 2017). Other initiatives have been more explicit in achieving a primary goal for a Lean healthcare initiative of doing more with less through rapid improvement events therefore leaving patient value as a secondary objective (Sanders et al., 2015). To improve healthcare, the Porter and Lee (2013) author argues, one must move from specialty activity to a “Value Agenda”. This “Value Agenda” or purpose of the system reflects Seddon’s (2005) views on understanding the purpose of the system rather than targets. This value agenda (Porter and Lee, 2013) must be supported by six components which are integrated practice units, measuring outcomes, bundling payments for care cycles, integrating care delivery, expanding excellence across geographies and build an enabling information technology platform. The concept of looking at more integrated care or widening the value stream is beginning to emerge in Lean and other healthcare improvements (McFarlane, 2014) which provide an opportunity to recognise that Lean healthcare has not been patient focused but provider value focused (Henrique et al., 2016).

In summary the overarching learning from a critique of Lean applied to healthcare is that there is no standard definition of what Lean deployment is therefore there can be some difficulty in comparing deployments or in being definitive that Lean is successful or otherwise due to the variety of "Lean" deployments styles and depths of implementation. Leadership in particular in healthcare can be challenging due to changes in leaders and Lean must assume a degree of change as improvements are being made with clear outcomes despite evidence of inadequacies in leadership. Addressing quality in healthcare is an area that attracts a lot of attention and is a potentially highly attractive as a route to adoption although implementations appear to believe there is a choice or trade-off between quality and productivity which is not reflective of Lean principles. Definitions of the value stream for the Lean case studies focus on providers and provider value not patient value. The concept of patient value is not clear in Lean literature and appears to be confused with healthcare provider value. To develop this understanding of why Lean should be used, it is worthwhile considering the appeal or motivation of using Lean. Figure 3.2 provides as summary of the key challenges and gaps to Lean in healthcare

Summary Points

Challenges

- Lean healthcare adding capacity and improving quality at lower cost(de Souza, 2009)
- Placing the patient as the customer of Lean healthcare, not the provider (Porter, 2013)
- Lack of consistent definition reflecting pragmatic practice rather than pure Lean (Young and McClean, 2007)
- Lean improvements evident, despite leadership instability (Burgess and Radnor, 2012)

Literature Gaps

- Limited literature linking quality issues to cost beyond Spears(2005)
- Lack of quality literature which evidences the benefits of Lean (Antony 2016)
- Lean value stream is provider focused preventing patient value being achieved (Radnor 2008b)

Figure 3.2 – Key Challenges and Gaps to Lean in Healthcare

3.3 The Appeal of Lean to Healthcare

To understand the potential of how technology can improve healthcare in line with the aim of the thesis it is worthwhile considering the appeal of Lean to healthcare as this may provide linkage to what works well for healthcare reform. Porter and Lee (2013) recognises that "hard work" and "well intentioned" clinicians are not sufficient and have little impact on the overall improvement of healthcare. Spears (2005, 89) highlighted that "Like many hospitals, Shadyside found that its nurses spent a disproportionate amount of time nursing not with the patient but the system – tracking down material, services and information." This leads to the assumption that working harder will not fix the problems but potentially increase the frustration of well-intentioned staff managing ambiguity, workarounds and medical errors. The Lean literature critique reveals a new element of why Lean is being applied to Healthcare that was not seen as clearly in other part of the public sector described in chapter 2 and this was that health providers are struggling to deliver healthcare in a time of rising demand, escalating costs and failure to make progress on core quality issues (McIntosh et al., 2014). Where (Radnor, 2009) had recorded the adoption of Lean in public sector was about proving effectiveness and efficiency when processing various government transactions Healthcare has an unmet need which “hard work” is not going to solve (Porter and Lee, 2013). The appeal of Lean in healthcare starts therefore from a need to find a new way of delivering healthcare. This new way of delivering healthcare has sought to utilise Lean in a number of ways or similar to the finding in chapter 2 Lean has been deployed in an inconsistent manner with various understandings of what Lean is (Samuel et al., 2015). Three key common groupings of approaches appear of across Lean Healthcare literature with these being; addressing quality, productivity and engaging staff.

Firstly, quality is evident as one of the main groupings as initiatives to improve patient safety and release “time to care” (White et al., 2017) have appeal both at the management level and staff level. Initiatives have recognised the linkage between benefits of safety and financial stability (Dobrzykowski et al., 2016) and some have targeted performance issues such as emergency department turnaround (Mazzocato et al., 2014). Spear (2005) identifies major quality issues with a particular focus on infection control. Similarly the Hospitals application of Lean (Wysocki 2004) to intensive care units discusses the use of one of the Lean quality approaches, known as the Andon Cord, where all activity is stopped until the quality issue is addressed. The approach led to reduction of infections which would have cost the hospital significantly and had a serious or critical impact on the patient. An approach which identifies and removes error is therefore appealing to practitioner, patient and commissioners.

Bowermann (2007) supports this opinion through the Royal Bolton NHS Trust implementation and discusses the Lean journey that began in late 2005.

Secondly productivity appears as a second main grouping in the purpose of Lean deployments. Specific measureable productivity outcomes including 42% reduction paperwork, reduced time to operating theatre, faster recovery time, reduced average length of hospital stay by 33%, blood processing reduced from 5 hours to 60 minutes and mortality reduced by 36% appear in one of the main NHS deployments of Lean (Bowerman and Fillingham, 2007). In addition, Bowerman and Fillingham (2007) reports on non-clinical improvement focused on laundry provision also releasing £300K in savings. Outside of the NHS other countries have reported on Lean implementations producing similar improvements such as reducing outpatient waiting times and labour productivity (Miller et al, 2015). Clearly these outcomes are appealing to both those working within the healthcare system and management alike. Similar outcomes are reported in Mazzacoto et al. (2010) with the most common improvements being; time saving, cost reduction, productivity improvement, quality improvement, staff morale improvements, patient satisfaction improvement and reduced mortality. Implementations additionally have reported improvements in terms of the number of patients being seen within the available time (Gavriloff et al., 2017). Time or costs improvement were frequently reported although a number of the academic studies have questioned the validity of the savings (Bowermann, 2007). For example in the event of a time saving, was this converted to a real cost saving or health outcome or was this just absorbed by the existing staff and costs within the system (Mazzacoto et al., 2010).

The third key group was around staff and finding new ways of working. Treasury (2009) report investigated the public service need for improvement. The report recognised that the Lean approach attempted to harness the knowledge of existing staff which was critical in gaining buy-in. Similarly Guthrie's (2006) work focused on the Royal Bolton hospital and draws out the staff engagement focus by highlighting "at its heart is a selective devolution of power to the shop floor, where workers redesign processes to raise quality and cut waste." The productive ward series which is heavily based on Lean appealed to staff by highlighting the benefits of releasing "time to care" with their initiatives which led to higher engagement from the staff in improvement activities (White et al, 2017). Young (2008) compares the concept of value stream mapping, used in Lean implementations, to the patient pathway which can be appealing to healthcare staff stating "The intuitive line between value streams and patient pathways is compelling…" This implies that staff engagement and a link to redefining patient pathways appeals to staff in a way that can often be absent in technology focused or top down reforms can be positive for staff. Lean interventions also reported positive impacts for staff such as reduced steps in a processing, reduced staff walking, increased process understanding, improved staff engagement, increased willingness to collaborate, calmer more focused working environments, reduced problem resolution time and improved error detection (Mazzacoto et al., 2010). These outcomes of fewer clinical incidents reduced medication errors and higher staff morale underlines the point of Lean quality leading to more productive staff with higher morale (Bowerman and Fillingham, 2007). In an environment with more pressure on staff than ever before and waiting lists set to rise by 25% to five million (Pym, 2017) there is an appeal to seeking reform options that engage staff.

In summary, the appeal of Lean in healthcare is multi-faceted as it impacts the patients, staff, managers, clinicians, and budget holders. Creating clarity, removing ambiguity, streamlining work activity, reducing paperwork time and addressing quality are all appealing to care providers. All of these are achieved through engaging frontline staff which again appeals to the culture of health providers. Some caution about the evidence of improvement (Morraros et al, 2016) and sustainability of improvements (McCann et al., 2015) are appearing in the Lean literature which repeats a gap emerging from the public sector Lean of a need for more evidence. Despite this caution, the healthcare demand to do more with less and to increase staff satisfaction is an appealing offering and in particular within a public healthcare system such as the NHS. To explore this further, the thesis will provide a literature critique of how Lean is used in healthcare by analysing the evidence based improvement opportunity of Lean, healthcare case studies and the approaches and tools used. This will develop the thesis in continuing to address objective 1 of a critical analysis of Lean related theory in healthcare reform and begin to collect relevant data to develop an initial theoretical framework to guide empirical analysis.

3.3.1 Evidence Based Improvement

An important point that emerges from the Lean literature which is relevant to its appeal is the use of scientific management underpinning as improvements sought empirical evidence (Samuel et al., 2015). This point can be missed in Lean healthcare implementations which focus on RIE's or improvement tools but an evidence based scientific management approach can be of value. This evidence base has parallels to clinical evidence based medicine such as demonstrated by the National Institute for Clinical Excellence for cardiovascular disease guidance (NICE 2017). Perla et al. (2013) draws this out by looking at the application of scientific and Lean approaches in healthcare and attempts to analyses options for hospital performance and the development of continuous improvement frameworks. The author explores opportunities with simple and complex patient pathways and the use of System Dynamics, Markov Model, Tree Diagram, Lean Thinking and Discrete Simulation. Lean has also been identified and deployed in healthcare as a tool to address statistically significant medication errors in their quality and implement a scientific management basis of improvement against "work progress factors" (Hussain, 2015). Similarly evidence of disappointing safety evidence for patients has been highlighted as a reason for initiating Lean with an expectation that these quantitative measures can be addressed through Lean where other softer management approaches may not be as evidence based (McIntosh et al., 2014). Lean scientific management approaches such as feedback loops, continuous improvement, testing and learning, plan-do-study-act cycle, repeatable process, variation control, predictive studies, multi-disciplinary, different states of stability all appeal to a science based healthcare (Perla et al., 2013). The Perla et al. (2013) article draws out the quantitative evidence base element frequently used in Lean when applied as a scientific management approach. The Plan Do Study Act (PDSA) cycles are relevant within healthcare as it brings an improvement focus of planning activities, measuring the outcomes, investigating the outcomes and implementing changes which then are part of cycle of continuous improvement. Clinical environments can be sceptical of improvement initiatives and Lean reviews will assess if this is the latest management fad to be endured (McCann et al., 2015) but the PDSA cycles applied to clinical environments provides a method to reassure clinical leads that the approach is not a latest management fad but has an evidence base.

A gap however emerges, linked to an earlier point from Samuel et al. (2015) where it was identified that there is no consistent definition of a Lean deployment therefore clinicians may see workshops and RIE events that do not introduce a scientific approach such as demonstrated in the PDSA cycles and therefore assume that Lean is a management fad in line with the McCann et al. (2015) critique. PDSA cycles can be found alongside RIE in Lean healthcare to support a need to build scientific management into the improvements (Bowerman and Fillingham, 2007) but this is dependent on the definition of Lean being deployed. Evidence based healthcare is a fundamental principle of western healthcare delivery and the use of scientific principles to achieve improvement in activities aligns with this basic principle. A Lean healthcare literature gap therefore is in understanding the level of adoption of continuous improvement deployments of Lean healthcare which could appeal more to clinicians versus the RIE events that are short term fixes. A reason for less focus on this aspect compared to manufacturing may be found in Radnor (2008b) public services reviews where it was believed that the basic data and process maturity was missing as a precursor to Lean improvements. This lack of maturity in process design means that baselines of performance are more difficult therefore applying continuous improvement requires the identification of baseline information. Other reasons of why scientific approaches may be missing in some healthcare examples may relate to a short sighted focus on rapid improvement events or tools which are later "diluted" and then "eroded" rather than continuous improvement culture (McCann et al, 2015). Continuous improvement examples of a scientific improvement which targeted a culture of improvement rather than a RIE event are however evident in healthcare (Manno, 2014) which takes us back to the point that Lean deployments are sometimes inconsistent in their application.

In summary the evidence base for Lean as a scientific approach is attractive to healthcare to address emerging failures in healthcare delivery around quality and safety. The link to a scientific approach for Lean can however be missed where basic building blocks of baseline data are not available or the purpose of the Lean implementation is short term in nature. Scientific approaches which focus more on longer term improvement through continuous improvement are likely to address concerns about Lean being a management fad and deliver better outcomes and buy in. To progress the main arguments it is important to look at specific healthcare case studies in the literature. This is to further understand Lean in Healthcare with the tools or approaches used which may be relevant in considering technology adoption in line with the thesis aim.

3.3.2 Healthcare Case Studies

To explore the key issues further, specific case studies have been examined to identify lessons learned and improve our understanding of how Lean healthcare can benefit from technology adoption. The approaches reflect different emphasises which are discussed below and includes;

- Lean tools and capability
- Focus on specific issues
- Continuous Improvement focus

The Lean tool focus reflected in Nord 92 hospital in France where "Lean as a learning system in a hospital" was implemented (Balle and Regnier, 2007). A significant number of Lean tools were applied which largely focused on clarity of roles. They attempted to develop an improvement or "Kaizen mentality" in the staff rather than "applying Lean tools to every process". Balle and Regnier (2007) however this draws out the details of an improvement process which took up to two years to implement and achieve results. Much of the recorded success was due to the improvements obtained by gathering the relevant process owners together as part of the implementation team. This research and the case study are significant as it reflects intent to utilise Lean as a capability development tool in itself as well as utilising specific Lean tools to fix a process. This capacity building is not always the case and a number of Lean implementation have clearly been focused on Lean tools to "promote individual innovation" (Lindskog et al, 2017). Within the Lean deployments, specific tools such as value stream mapping, waste identification, root cause analysis and visual management appear frequently (Miller et al., 2015).

This tool focus can be less dominant in other Lean applications which focus on specific issues within hospitals such as the Royal Bolton NHS Trust which linked an improvement journey to address specific issues and create the Bolton Improving Care System (Bowerman and Fillingham, 2007). Their approach used a series of RIE and focused on areas of specific need such as high mortality rates. Bowerman (2007) argues that this approach with Lean can save lives and has positive staff outcomes such as “a touch of inspiration” on staff attempting to improve the service they deliver. Bowerman (2007) highlights specific issues in healthcare such as drug errors, falls, infections and misdiagnosis which can have a direct impact on lives, costs and efficiency which can be addressed in Lean deployments. The Bolton deployment is a seminal deployment of Lean within the NHS and documented in Bowerman and Fillingham (2007) and de Souza (2009) which are both heavily cited papers. The approach however of targeting specific goals in healthcare has been repeated in other Lean implementations since which address areas such as reduced infections, reduced waiting times, reduced mortality (Moraros et al., 2015). Similarly the “Productive Ward” series has focused on specific quality issues and utilises Lean to address these (White et al., 2017). The approach has some degree of benefit in gaining buy in from staff and providing some focus for the project with significant benefits centred around a shared goal and diagnostic turnaround time for specimens in emergency departments (Sanders and Karr, 2015). This outcome focus instead of a tool focus may provide some insight into gaining buy in for healthcare staff with a common and shared goal in the outcome rather than learning Lean tools. This outcome focus may however reflect a short term wins approach which Lummus et al. (2006) draws out from the learning within a mid-western USA clinic. The case study discusses a busy medical facility with various disciplines and departments. With the assistance of Lean experts unfamiliar with the medical environment they mapped the current state and considered the various wastes, inconsistencies, and errors created prior to creating a future state. The future state was made up of various scheduling boards and processes to reduce wait and make decisions quicker. As a result the patients had a faster smoother process but the Lean application is limited to making a specific processes faster and does not question the value being delivered other than within the restrictions of this care provision facility. Similarly, Hayes et al. (2014) investigates applying Lean flows in pathology laboratory remodelling and explores the use of Lean in Campbelltown Hospital in Sydney, Australia. The example provides wastes in overproduction, motion, transport, repeats due to error and exploration of the use of “Takt” time in reform. This also draws on the experience of reform and linkage between the emergency department and the supporting pathology laboratories. RIE’s involving the two departments was used to explore new approaches and the results provided were positive for patient and healthcare provider. Again there was an attempt to make a process faster however limited exploration of value with the assumption that faster with less errors by the care providers is better. There was however limited questions about if the service was needed or was it delivering the right service mix. The approach is also somewhat short sighted as rapid improvement events provide short term improvement and excitement but fail to unpick route cause issues or build an approach to address changing needs in healthcare. For example as healthcare demands change but the process remains the same a RIE with and outcome focus will have a decreasing return as the solution quickly becomes out of date and the initial staff involved in the RIE move on to new roles. A gap or critique of the literature is around the long term value of the improvement as a short term measure may be to create measureable value made but can it be sustained and does it consider real value for patients or just process value? This leads to a critique that continuous improvement or the Lean principles of perfection (Womack et al. 1991) are missed from the delivery. The culture of improvement again is not addressed but simply short term improvements which leads to the question of a third approach around continuous improvement.

In the tools and outcomes focus one can see evidence of engaging staff for early wins which can be attractive. This however does not necessarily adopt a culture of improvement and the absence of this improvement culture could lead to gains being "eroding" over time (McCann et al., 2015). In contrast to a short term win approach, Virginia Mason Hospital introduced a Virginia Mason Production System based on a longer term investments (Kaplan and Patterson, 2008). Over a 6 year period the outputs were reduced capital requirements, reduced inventory, reduced staff walking, reduced labour and reduced patient treatment time. Similar longer term investments reflect "culture change" within the organisation and moving from reacting to the latest crisis to having "methods, processes, and strategies" which address emerging issues (Mannon, 2014). In the Virginia Mason Production System over 8000 patient safety alerts were raised which highlighted the volume of quality issues that in a normal healthcare environment would be unresolved however a system was introduced to address quality and safety issues, defect rates, labour process issues, medication errors and wasted capacity. Some of the key implementations included standardisation of significant parts of the business through a modified 5S and introduction of a "Quality Safety Alert". The safety alert was similar to a Lean "Andon Cord" in a classic Toyota quality management system where work is halted until the quality issue is resolved. The tools and approaches therefore in this example reflect longer term capacity building integrated with specific improvements within a continuous improvement environment. Where criticism has been directed at Lean there is often a misunderstanding of the potential of Lean in continuous improvement and a poor definition of Lean being linked to tools and RIE. This is reflected in

Kolberg et al. (2017) where the authors had such a narrow view of Lean that they began to build in other factors beyond Lean that would be part of a continuous improvement approach. This again reflects Samuel et al. (2015) finding of a lack of consistent definition leading to criticisms that may not be accurate. Similarly the criticism of Lean not delivering improvements can show evidence of comparing short term tools approaches with continuous improvement approaches leading to a poor comparison (Moraros et al. 2015).

In summarising the various approached of the case studies one can draw some differences between shorter term problem based initiatives or tools focus against longer term continuous improvement approaches. The continuous improvement approaches can be difficult to maintain due to changes in leadership (Radnor 2013) but provide larger gains which are more sustainable (Mannon, 2014). The short term problem based or tools can bring some early buy in and early evidence of improvement but evidence suggests this will be diluted with time and may lead to a frustration that Lean is just a fad. The next section outlines the opportunities and tools used in Lean improvements across the literature this contributes to the understanding of where technology could assist in addressing waste.

3.3.3 Approaches and Tools

The application of Lean as an approach to improvement in healthcare is the most frequently documented approach in literature (Mazzocoto et al. 2014). Lean healthcare literature and about deployments is dominated by the UK and USA but continues to extend to other countries such as Brazil and the Netherlands (Costa et al., 2016). The Saskatchewan deployment of Lean is notable as the largest deployment in healthcare and utilises outputs such as the productive ward series from the NHS in its deployment (Kinsmen et al., 2014). Other notable deployments include Sweden where 9 out of 10 hospitals have a claim of implementing some level of Lean. Key Lean deployments are detailed in table 3.1 with the aim of drawing out the main Lean tools and improvement opportunities which will be summarised after the table. From this review of existing Lean Healthcare literature the thesis will begin to develop a theoretical framework of where Lean is used and the tools supporting this use. This will provide a theoretical framework to be applied to empirical evidence in line with objective 1 and 2. The Lean literature is critiqued to focus initially on the UK NHS and USA deployments due to these being the key promoters of Lean in healthcare (Mazzocoto et al. 2014).

Table 3.1 – Lean Tools Applied in Healthcare

Health Provider	Tools	Improvement Opportunities	Reference
Virginia Mason Medical Centre, Seattle **Schon Klinik** **Cleveland Clinic** **Geisinger Health System**	Integrated practice unit, patient focus, organised around medical condition, review performance data and address lifestyle change.	Duplication of effort, delays, inefficiency, lack of coordination, less staff absence, fewer physical therapy sessions, lower MRI use, fewer strokes, amputations, less ED visits, better outcomes and increased throughput.	Porter and Lee, 2013
Virginia Mason	Process improvement workshops, 5S, value	Staff walks, reduced	Kaplan and Patterson, 2008

	stream mapping, everyday Lean, Kanban to improve flow and Andon Quality Chord	inventory, lead time, quality and safety issues, defect rates, labour process issues, medication errors and wasted capacity	and Wysocki, 2004
UK and Sweden	Flow model	Waiting	Kollberg et al., 2007
UK and USA	Interruptions, delays and mistakes and improving the flow of patients.		de Souza, 2009
NHS, England	Productive Ward		Edwards et al., 2012
Royal Bolton Hospital - NHS Foundation Trust Hospital	Bolton Improvement Care system – Kaizen event, PDSA cycle for scientific improvements and staff engagement.	Reduced patient falls, reducing mortality in hip replacement, reduced deaths, blood processing turnaround time,	Bowerman and Fillingham, 2007 - Guthrie, 2006
UK Emergency Departments		Reduced waiting time, improved care, process flow	Silvester et al., 2004
Health Service Scotland		Wait time to first appointment	Radnor et al., 2006

		reduced, higher productivity, customer flow time	
Saskatchewan Healthcare (Largest Lean Transformation in the world)	Productive ward: releasing time to care. Kaizen promotion offices leading skill development.	Targets of faster access, emergency waiting times and zero defects.	Kinsmen et al., 2014
Ireland – Productive Ward, Releasing Time to Care	Visual management and streamlining processes.	Patient safety, reducing harm, reduced absenteeism and reduced hospital acquired infection.	White et al., 2017
Emergency Departments - Sweden	Process flow and removing waste.	Reduced waits and Reduced Length of stay	Mazacotto et al., 2014
USA hospitals including - Western Pennsylvania Hospital	Rapid experiment techniques. Roles, responsibility and Instruction.	Work in progress, staff time and infections	Spear, 2005
Anonymised healthcare provider referred to as Case Study A	RIE, employee development, process capability and continuous improvement.	Lead time, process time and activity steps.	Radnor et al., 2008
Anonymised		Diagnostic wait	Radnor et

healthcare provider referred to as Case Study G		time.	al.,2008
5 Hospitals, Wisconsin, USA	Culture of change, visual management and daily continuous improvement	Improve Quality and prevent need for crisis intervention.	Mannon, 2014
Three Hospital Deployments	RIE, data driven projects, cell/team work – continuous improvement teams, visual management, KPI’s, process mapping, time and motion studies, theory-of-constraints, Lean tool training, 5S/6S and cross functional work.	Unnecessary steps and quality defects.	Burgess and Radnor, 2013
Nord 92, France	Addressing standards, work instructions as part of the reform work.		Ballé and Régnier, 2007
City Hospital Birmingham	Reducing variation	Lower waiting time	
Flinders Medical Centre, Adelaide		Reduce Emergency Wait times, stress,	Gubb and Bevan, 2009 & Lummus et al., 2006
Progressive Healthcare	Value Stream Mapping, standardise operations, improve workflow, organise workplace	Reducing waste	Bushell and Becky 2002, & Lummus et al., 2006
Allegheny General	Flow, root cause,	Reduce	Wysocki, 2004

Hospital, Pittsburgh	analysis, Value Stream Mapping, Kaizen, Andon Chord equivalent/root cause analysis,	infections and reducing costs.	& Lummus et al., 2006
Medical Clinic, Mid-Western USA.	Value Stream Mapping, Observation, measurement, visual management,	Address staff shortages, overworked, and staff turnover, 25% increase in capacity, speed-up recovery cycle.	Lummus et al., 2006
IOM Process Improvement Methodologies Review	RIE, 5S, Lean production, flow, Value Stream Mapping, standardisation, root cause analysis, visual management, DMAIC, control charts and bench marking.	Reduced cost, improved quality,	Radnor, 2010
Nebraska Medical Centre		Reduce staff walking, remove bottlenecks, improve labs turnaround, less staff, reduced average length of stay (ALOS)	Fosdick and Uphoff, 2007
Pathology Labs, Campbelltown Hospital in	Gemba, RIE, transport diagrams, TAKT time, seven flows,	Faster turnaround time, calmer	Hayes et al., 2014

Sydney, Australia		working environment, increased pace of work, increased job satisfaction, overproduction, motion, transport and repeated activities due to error.	
Swedish Health System Example	Flow based evaluation	Delays, preparation time reduced, referral management and booking procedures.	Koolberg et al., 2006
Louisiana – 2 Hospitals, USA	Time analysis, cost analysis and visual management	Prescribing errors, equipment waits, transcribing and dosage delays.	Ker et al., 2014

A critique of some of the key deployments is that recent literature has focused on deployments begins to repeat itself with limited development of the Lean approach to healthcare. Also more recent literature reveal less new tools and approaches due to a lack of development and focuses more on niche areas such as facility design (Hicks et al., 2015), dissemination strategy (Dannapfel et al.,2014), “staff perceptions of Lean” (Kaltenbrunner et al. 2017) and measuring levels of engagement (White et al., 2017). This lack of development in Lean literature may reflect a lack of novelty for academics but not necessarily any less buy in from government and practitioners (Samuel et al., 2015). Recent deployments repeat the experience of the early work from the NHS with both Saskatchewan (Kinsmen et al., 2014) and Ireland (White et al., 2017) mirroring the productive ward work. Similarly the work in Virgina Mason, USA has being replicated across other USA hospitals with limited development of the tools or approaches.

The aims and objectives of this research is to utilise learning from Lean interventions and explore the potential for technology to address potential improvements either in patient enhancing patient value or addressing waste. The improvement opportunities and tools identified in the literature are therefore useful in considering the application of technology as it provides an unmet need to address. From the literature regarding the applications of Lean as an improvement approach, the following list consolidates the wastes that have been identified in the case studies. These wastes while negative in themselves identify potential improvement opportunities within healthcare and provide an opportunity to develop theoretical framework to be applied to empirical evidence at a later stage in the thesis. The consolidated wastes are shown in 3.2.

Table 3.2 – Lean Waste Categories Identified in Lean Healthcare Literature

Consolidated Waste Category Identified in Literature 3.1	***Example***
Waiting times	*Awaiting treatment to begin*
Delays	*Waiting for activities, results while being treated*
Activity Transaction Speed	*Related to activities within the value stream*

Diagnostic	*Turn-around times*
Medical Complexity	*Increasing strokes risks and amputations*
Additional healthcare Visits –	*Follow up, review or further appointments than necessary*
Co-ordination of healthcare resources	*Often lack of coordination producing additional activities*
Stress/overload of staff	*Often drive by lack of clarity and inefficient processes*
Repeated Procedures	*Missing test result, records or updates requiring repeated work*
Motion/Transport	*Including staff walking*
Length of Stay	*Average length of stay is a key measure of hospital performance but needs to be balance with readmission rates*
Cost	*Wasted money and processing additional claims or costs*
Quality	*Errors in practice or administration of care*
Emergency Admissions	*Unplanned, avoidable admissions regarded as a failure in the system. For example an escalation in a condition which could have been prevented.*
Death	*Unnecessary mortality due to falls, infections, Turn-around times*
Medication errors	*Wrong drug, dosage or administration*
Infections	*Caused by the medical interventions or environment of medical intervention.*

The review of the Lean healthcare literature also identified a consolidated list of Lean tools used in healthcare which are of significance as Lean practitioners will adopt and adapt the relevant approaches based on the presented needs and the outcomes as summarised in Figure 3.3

Lean Tools Identified in the Literature

Lean Healthcare Tools

- Value Stream Mapping
- Rapid Improvement Event (RIE) /Kaizen Event
- PDSA/Scientific improvement
- Cell/Team/multidisciplinary work
- Andon Chord/ Quality Escalation approach
- 5S/Variations to organise workplace
- Standard Work/Defined Roles and responsibilities
- Integrated Practice Unit
- Reviewing Performance Data
- Gemba – Go and See
- Takt time – timing and demand based output
- Kanban – availability of inventory at right time
- Root Cause Analysis/5 Whys - discovering underlying issues and causes
- Seven Flows – reviewing people, information, material, sub-assembly, finished goods, machines and engineering.
- Mistake Proofing – implementing procedures which prevent error
- DMAIC -control charts and bench marking.

Figure 3.3 – Lean Healthcare Tools from Literature

What is clear from the improvement opportunities and tools used is that the wastes or opportunities often come at the join between people and disciplines. The tools such as value stream mapping and RIE which are frequently used across the literature, bringing staff from overlapping areas together in a structured manner to generate ideas and help to facilitate innovation within the staff (Lindskog et al., 2017).Visual management tools also appear frequently with some of their use being in facilitating continuous improvement (Mannon et al., 2014). This is an important point when considering how technology can strengthen healthcare reform and identifying areas for improvement. 5S also features heavily as a method of bringing discipline and simplicity to a pressurised and complex environment where equipment not being available or simple mistakes can have catastrophic consequences (Delise et al., 2014).

Summarising this section the following key challenges and gaps identified have been identified along with key Lean healthcare wastes and tools. The Lean healthcare wastes are relevant to creating a theoretical framework for exploring empirical evidence to be applied to at a later stage to consider the relevance for technology. The next section moves on to addressing specific challenges and barriers in adopting Lean in Healthcare. Figure 3.4 provides a summary of the Lean Healthcare Approaches in the literature.

Summary Points 3.2

Challenges

- Lean healthcare adding capacity and improving quality at lower cost(de Souza, 2009)
- Placing the patient as the customer of Lean healthcare, not the provider (Porter, 2013)
- Lack of consistent definition reflecting pragmatic practice rather than pure Lean (Young and McClean, 2007)
- Lean improvements evident, despite leadership instability (Burgess and Radnor, 2012)
- Productivity Challenge – Quality and Lower Cost (McIntosh et Al., 2014)
- Need for Staff Engagement (White et Al., 2017)

Literature Gaps

- Lean literature around tools and approaches not developing since 2010. Repeating experience such as Saskatchewan (Kinsmen et Al., 2014) and Ireland (White et Al., 2017).
- Limited literature linking quality issues to cost beyond Spear(2005)
- Lack of quality literature which evidences the benefits of Lean (Antony 2016)
- Lean value stream is provider focused preventing patient value being achieved (Radnor 2008b)

Figure 3.4 – Summary of Lean Healthcare Approaches

3.4 Challenges to Lean Healthcare

While there are significant reasons why a Lean approach is attractive there are also a number of key challenges in addressing these improvements. These are documented in the sections below and are important to consider as part of investigating technology options. These challenges are;

- Leadership and buy in
- Redefining value and demand
- Lack of system thinking
- Limited reference to technology adoption

3.4.3 Leadership and Buy in – We are Not Japanese and we don't make cars

The concept of buy in is a challenge for Lean due to it being adopted from the manufacturing industries since 2000 (Samuel et al., 2015). As the Lean approach has been sourced from manufacturing one cannot assume that the approach can be translated to healthcare without adaption (Bowerman and Fillingham, 2007). A notable difference from the early Toyota production system and healthcare today was that that the Toyota developments removed waste to allow better efficiency during low post war demand where in contrast the NHS and other health systems today are attempting to remove waste to manage high demand. (Ohno, 1988). Bowerman and Filligham (2007) highlights Lean adoption issue at the Royal Bolton NHS Trust by revealing practical difficulties of implementation in terms of releasing capacity for training and service improvement initiatives such as RIE. The report states that staff may have an attitude of "we're not Japanese and we don't make cars" (Bowerman and Fillingham, 2007, 232). This was reflected by Wysocki (2004) in his Wall Street Journal article which discussed the possibility of hospitals taking tips from the manufacturing factories. In this article one of the trainers commented that "Doctors, nurses and other hospital staffers don't' think of themselves as assembly line workers or their patients as anything resembling a Camry (Toyota Car) under construction” (Wysocki, 2004, 2). Similarly Waring and Bishop (2010) makes reference to the staff resistance which was documented in the business process improvement methodologies 2009 report (Radnor, 2010).

Beyond the specific issues of adopting approaches from manufacturing is the issue of gaining staff buy in. Quality improvements in healthcare are clearly needed due to increases in demand from an ageing population but have typically failed to engage clinicians and healthcare worker leading to questionable results (White et al., 2017). Change can be difficult as healthcare is in a constant state of reform and practitioners can be wary of the latest improvement initiative and attempt to understand if this is just another management “fad” to be weather rather than adopted (McCann et al., 2015). A lack of staff commitment and buy in can lead to both poor results in performance improvement or reduced performance improvement (Chiarini et al., 2016). Staff can however recognise that Lean can provide an opportunity to address the “Chaos” of the current roles and bring some degree of order and control which can specify activities and address frustration in organisation design (Roszell et al., 2014). This new level of flow and control can result in a less reactionary environment to one of more control (Mannon, 2014).

Related to the staff buy in issue is the area of Leadership. Burgess and Radnor (2012) reports on NHS service improvements, discussing the issues and necessity of strong leadership in healthcare reform. The most significant findings from their research relates to the learning around the impact of leadership on Lean implementations. This is reflected in the “Gemba” tool which appears in a number of the Lean Healthcare literature case studies and encourages leaders to go and see the healthcare activities themselves which encourages a “Lean leadership mind-set” (Aij, et al., 2015). Leadership change can however be an issue in healthcare as Burgess and Radnor (2012) report that in one trust during a three year implementation period the chief executive had changed three times and the chief operating officer had changed five times. This was reported not as an outlier case but a normal pattern with NHS chief executives lasting on average 23 months in post. Burgess and Radnor define the NHS environment as in "persistent policy reform, reduced budgets and tough regulation" (Burgess and Radnor, 2012, 1) which leads to high turnover of senior staff. The changes at the senior level, awaiting new direction and conflicts of policies as the old direction and new directions overlap each other were clearly outlined as impacting the Lean implementations. It was however notable that despite this lack of stability and the lack of clear direction, all three of the case studies had evidence of a positive impact for Lean "leading to numerous improvements large and small" (Burgess and Radnor, 2012, 8). Where Lean change programmes have not been sustained or have succeeded there is largely a link to the success of employee engagement and clear leadership (Lucey et al., 2005). This need for leadership also reflects the difference between a short term gain which focuses on the tools but is unsustainable and a longer term continuous improvement which may need to address functional silos in the organisation (Van Rossum et al., 2016).

In summary, one cannot assume Lean is without challenges as the issues of translating Lean from manufacturing, gaining staff buy in for hearts and minds is difficult as it engages the logic of improvement as well as the emotion. This is highlighted in White et al., (2017) where the logic of the engagement was agreed but the programme then adopted the marketing concept of "releasing time to care" to engage a more emotional side of the change. In addition the practical consideration of releasing time to enable attendance at workshops and RIE events is raised in a number of the literature reviews. Finally, the issue of leadership buy in is a difficult area as it is assumed that leadership buy in is a pre-requisite of a successful

Lean implementation; however the reality is that Healthcare leadership is in a constant state of flux.

3.4.4 Redefining Concepts such as Customer Value and Demand

A key critique of the Lean literature is that it reflects processes and provider value and not patient or customer value. For example providers may recognise a "perfect storm" in healthcare but the Lean application assumes addressing improvements in the hospital rather than considering if the service which they are attempting to streamline is delivering value for the patient or will meet the need of this perfect storm (White et al, 2017). Similarly Lean in an emergency department focuses on turn-around-time for samples in the emergency department but assumes that patient value must start with the arrival at the emergency department (Sanders et al., 2015). Limited questions are made about why the patient had to go to the emergency department and if this is an escalation of a health condition that could have been detected prior to needing to visit the emergency department. The critique therefore is that if the first principle of Lean is to focus on value for the customer (Womack et al. 1991) then the question of value must rest with patient value and not with the provider such as the Emergency room. Initiatives outside of Lean such as Accountable Care Organisation (McFarlane, 2014) have sought to redefine delivery and consider bundles and packages of care that cross silos in healthcare but this is absent from most of Lean healthcare literature. The literature focuses on productive wards (White et al., 2017), clinics (Mannon, 2014), labs and emergency departments (Sanders et al., 2015) which represent provider value not patient value. Porter (2010) explores and challenges the clinical professions understanding of patient value by arguing that healthcare is measured in volumes of procedures and shifting focus to value or outcomes must be a central challenge. Reforms which focus only on activity and cost reduction with no regard for the outcomes achieved is dangerous and often a false saving which could potentially limit care. There is a tension between healthcare leads and clinicians as they attempt to improve patient throughput, resource utilisation and co-ordinating staff while minimising disruption (Waring and Bishop, 2010). The competing priorities of staff, budgets, waiting lists and the need to clearly articulate common goals around patient value are potential barriers to improvement and must be addressed. Porter (2010) takes this further by arguing that limiting care can create a need to spend more on other services therefore becomes a false saving. The view of not defining value properly is supported by Young and McClean (2008) which provides a discussion on the concept of value to a single customer and notes the complexity around this in healthcare. Radnor (2013) provides a more robust attack on Lean deployments and states there is a “lack of understanding of the centrality of the customer..” which is linked to the reason for failures in implementations. Her conclusions also point towards a need for a deeper understanding or “end user value”. While Radnor is pointing at this gap in the Lean deployments her criticism is still within the context of hospitals and failing to go far enough in identifying the real patient value which may relate as much to prevention an avoidance of hospitals as Value within a hospital. Porter (2010) extends the idea of patient value proposing that healthcare outcomes need to be specific to the medical condition. Rather than a need for “focused factories” there is a need for integrated care units which bring together the care needs of a patient. He states that these should track patient outcomes and cost across the long term care of the patient and patients with multiple conditions should have risk adjustments made to understand their care and related costs. Similar to Radnor, Porter is still viewing the patient value within the confines of healthcare delivery and not patient value which may include avoidance of care. Linked to this narrowness of focus on patient value is the topic of measurements within the hospital and with healthcare providers. The current Northern Ireland NHS measurements (Information & analysis directorate, 2017) are largely around clinical activity measures which are too narrow for patients and what the hospital does is too broad to be of concern to a patient. Porter (2010) highlights that measuring performance based on what is billed does not align with patient values or needs therefore we need a redefined patient focused value. Waring and Bishop (2010) supports this view of redefining value as he highlights a number of lessons learned. Of particular relevance are the need to avoid healthcare provider interest in specifying value, the use of flow for inter-disciplinary approaches and the need to avoid negative arguments of efficiency versus quality.

To emphasise this point about not understanding what value is or how to measure it, Porter (2010), points to quality and process measures found in healthcare effectiveness data and information set measures. He emphasises that 73 of the 78 are process measures and not outcome measures. In the article he proposes a switch to a more appropriate patient value and breaks this down into three tiers;

- Tier 1 - Health status achieved or retained
- Tier 2 - Process of recovery
- Tier 3 - Sustainability of health

In the Royal Bolton NHS trust (Bowerman and Fillingham, 2007) Lean implementation the definition of value was explored using a number of tools. These included observing, patient diaries, questionnaires, interviews and focus groups. The report on the Lean implementation recognised that this was a challenge to the staff as the perception was that staff knew what patients wanted already without the need to explore this. Through the exercise; areas such as pain relief, information clarity, coordinated information, cleanliness, hygiene and infection were all raised as part of patient value therefore the definition of value even in a restricted hospital setting was extended substantially. From the patient value definitions they were then able to create better value stream maps detailing the patient journey from arrival at A&E, transfer to wards, transfer to theatres, transfer back to wards and finally to discharge.

Reinforcing this view that the staff may not know what is value for the patient is Porter and Lee (2013) report on "strategy that will fix healthcare". He notes that "entrenched interests and practices" are part of the need for transformation and can present as a barrier. Payment structures and structures which have been in place for decades are believed to reinforce or incentivise problems which produce "erratic quality and unsustainable costs". Young and McClean (2008) provides a discussion on the concept of value and comparisons to quality adjusted life years (QALY) as perhaps helping to define value from a patient view but again complexity is added as patients will have a wider view of value that QALY. The research summarises value as having three dimensions; clinical, operational and experiential. The research also highlights Lean in healthcare as having an absence of a single customer. The review looks at the role of IT and medical device manufacture in understanding value as the role definitions built into the user requirements provides some insights. Additionally their review of Lean comes to the conclusion that patient value should be defined within the scope of the healthcare provider. Although this is useful it still limits the outcomes to the hospital location which is different to Porter (2010) review which recognised that value will extend beyond the hospital to recovery time and return to maximum function. Similarly Olga and Brown (2016) conclude that Lean in Healthcare in the NHS must move to improving the whole patient journey. In the USA healthcare system there are exploratory moves towards "Value based reimbursement" which encourages payment incentives for the care provider to meet the needs of the patient rather than the system (Porter and Kaplan, 2016).

Moving beyond the question of what is value from a patient perspective to redefining demand which is linked to Lean tools such as value stream maps Lindskog et al., (2017) explored the Swedish health system. It had difficulty with demand as the concept of a presenting demand being different from delivered demand will create issues for Lean as the presenting condition of an aching leg may end up with a heart transplant following assessment and diagnostic work (Kollberg et al., 2006). From this there is a recognition that where the demand for a Toyota car may be a reasonably solid concept with limited complexity linked into managing sales variability, in healthcare however there is a lack of clarity about what demand is and competing organisational goals adding to the treatment complexity (Dobrzykowski et al.,2016) . Understanding demand is challenging and specifically understanding if long waits are a mismatch of demand and capacity are important questions (Silvester et al., 2004). While it is recognised that an ageing population is bringing additional demands to the healthcare system (Dannapfel et al., 2014) there is a lack of exploration of what healthcare demand consists of and if the demand is valid in Lean healthcare literature. Related to this is the concept of failure demand that is again not evident in the Lean healthcare literature (Seddon, 2008). For example a GP visit may reflect loneliness rather than a healthcare need but the clinician must deal with the presenting patient. Similarly, a patient may attend A&E because their need was not met by a GP. This is a relevant Lean healthcare question and one which is not easily answered as a broken bone may have a clear need for A&E however there are significant number of patients attending GP’s or A&E with mental health or alcohol related issues which may be due to a failure elsewhere to address their need. This concept of failure demand would not typically be addressed by Value Stream Mapping applied to the A&E process as it would be assumed that all demand is valid and should be addressed as part of the process. This lean Healthcare literature gap of understanding failure demand is therefore important for Lean as well.

In summary, definition of patient value will need to be redefined beyond traditional approaches that focus on the activities and providers towards value that has the patient at the centre. Secondly the concept of demand needs to be questioned and understood as presenting demands may not be appropriate and may represent failure elsewhere. The area of demand is not served well in Lean literature as most focus is on processes.

3.4.5 Lack of System Thinking: Single Discipline Focus

The next challenge is the lack of system thinking. The role of Lean has been shown to provide evidence of improvement and outcomes based on measures within the existing practice (Mannon, 2014). It could however be argued that it is limited in its scope as it has been practiced. If Lean is not widely deployed it will be some time before cross department and cross organisations will be demonstrated to reflect a true Lean focus on the patient rather than the provider de Souza (2009). A review of classifications and analysis of Lean literature investigated developments 5 years after de Souza's work and found little development of thinking and implementation (Costa and Godinho, 2016). Costa and Godinho (2016) did however note that some work was moving to implement Lean across a hospital as a whole. Although this is encouraging it is still a significant distance from a patient view of value across their care provision. Similarly Mazzacoto et al. (2010) reports that the scope was found in most cases to relate to a specific process in a specific location with very little evidence of organisational boundaries crossed. The study concludes that "while Lean theory emphasises a holistic view, most cases report narrow technical application with limited organisational reach." The early focus of Lean was on single hospital wards and not necessarily considering multiple elements of a patient journey (Spear, 2005) and largely this has not changed in more recent publications such as within the productive ward series (White et al., 2017). Balle and Regnier (2007) again focused on individual hospital wards and Young and McClean (2008) notes the lack of longer term initiatives. Radnor (2009) highlights the piecemeal approaches that have been evident and Waring and Bishop (2010) focused again on a narrow scope, not reflecting the need to cross organisational boundaries or consider full patient journey. This point emerging from Lean is focused on the provider rather than the patient as emphasised in a closing statement in the abstract of Hwang et al., (2014) where it states that “nursing practices …. are good candidates for lean practice” as this highlights the focus on the on making the provider Lean rather than an understanding of lean value stream delivering value for the patient.

A second point on the lack of system thinking is related to sustainability. The topic of sustainability is covered by Young and McClean (2008) noting that long term embedding in the culture is more difficult to achieve. The benefits which start well but evaporate as good intentions disappear and changes in staff impact the improvement (McCann et al., 2015). The literature research also notes the lack of longer term initiatives beyond the simplistic process mapping and a lack of transferring best practice beyond the initial learning site (Matthias et al., 2016). A focus or over-reliance on Lean workshops and tool kit approaches are perceived as challenges to the long term success of Lean (Burgess and Radnor, 2013). The 2009 Operational Efficiency Programmes Final report (Treasury, 2009) reflects this position by highlighting the need not only to deliver improvement programmes but also to build the capacity and capability within the system to introduce and manage continuous or longer term improvements.

In summary of this section one can find that the approaches taken have been narrow in scope, not crossing boundaries to reflect patient value. Secondly the approaches often fail to grasp longer term continuous improvements that will last beyond the initial improvement.

3.4.6 Limited Reference to Technology Adoption

The final Lean healthcare challenge or criticism of the literature is the limited reference to technology as a potential route to improvement. Throughout the Lean literature review a small number of references have been made to technology such as the need to invest in technology to consolidate patient information, scheduling, medication, clinical support, and communication with professionals (Porter and Lee, 2013). A limited reference is made to medical device manufacturers design in defining who the customer is but not as a tool to improvement (Young and McLean, 2008) and medication distribution systems appear in Lean literature (Ker et al., 2014). One of the few articles bringing Lean, healthcare and technology together is Yusof (2012) which provides an "Evaluation of the clinical process in a critical care information system using the Lean method". This provided a case study focused on lean applying to system development. The work targets a critical care information systems which provide - charting, vital signs, bedside device data, laboratories, pathology reports, medication orders, planned interventions, nursing care, anaesthesia care and surgical care. The author attempts to understand technology opportunities in line with the Lean opportunities to consider waste in the processes. As part of this application wastes were identified in delays to start, delays to patient readiness, lack of consistent process and communication with staff with Health Information systems being part of the improvement technologies. The article is limited in scope but does provide some potential notes on the use of technology.

In light of this positive role that healthcare technology can have in Lean deployments and addressing patient value the absence of Lean healthcare technology is a significant gap in deployments. Technology can create significant improvements in care provision and this has been proven with from providers who have taken this approach Porter and Lee (2013). In

Lean literature previous gaps have emerged that could be addressed by technology but these are not explored in Lean literature but will be addressed in this thesis. In summary a number of key points emerge that are summarised in figure 3.5.

Summary Points 3.3

Challenges

- Need for Staff Engagement (White et Al., 2017)
- Need for Leadership to enhance benefits (Burgess and Radnor, 2012)
- Lack of sustainability (McCann et Al., 2015)

Literature Gaps

- Lean healthcare does not address patient value but focused on provider value.
- Lack of discussion on understanding demand in Lean healthcare
- Lack of consideration of failure demand in Lean healthcare literature
- Healthcare technology absent from Lean deployments or addressing lean wastes.

Figure 3.5 – Summary Diagram 3.3

3.5 Summary of Lean Healthcare

In summary the literature critique shows that far from Lean being inappropriate in healthcare there is significant learning to adopt (Mannon, 2014). Large returns for public services have been experienced in trials of Lean and this reflects the "low hanging fruit" due to the lack of processes or organisation (Radnor, 2008). There is sense that approaches are only currently scratching the surface of potential improvements in healthcare. The evidence of appetite may reflect similarities between patient flow and the manufacturing process. The approaches which encourage staff engagement and the high focus on quality as a means to improvement are encouraging to health providers seeking improvement opportunities (White et al., 2017).

In addition to the appetite there is empirical evidence of outcomes (Samuel et al., 2015). Examples of these healthcare outcomes reflect the identification of wastes such as staff travel, waiting for equipment, waiting for medicines, lack of out of hours capability, waiting for referrals, excessive process time, diagnostic wait time, unnecessary steps, reworking activities, quality defects and many others. These reflect a large return for investment for the improvement programmes.

Challenges will need to be addressed in capability as the sustainability of improvements are questionable beyond the Rapid Improvements Events (McCann et al., 2015). Also the scope appears too narrow and doesn't focus on real value for patients beyond a clinic or hospital which will be demanded to meet the challenges of long term conditions.

There are unresolved gaps between the Lean healthcare identified in the literature and the definitions of Lean. There is a need to understand patient value and not the healthcare provider which is what emerging approaches such as accountable care organisations are attempting to do in the USA (McFarlane, 2014). There will need to be a wider investigation into the purpose of the system to understand how to get all staff to look for improvements rather than improve a distinct process. As part of understanding patient value one can also begin to understand if the presenting demand is valid demand or failure demand.

Finally, there is limited reference to technology adoption in Lean reform therefore further investigation beyond Lean literature is needed to understand the role of technology in healthcare improvement to address the aims of this thesis. This will be explored further in the next chapter.

Chapter 4 - Technology Healthcare

4.1 Introduction

The aim of this thesis is to explore the role of Lean thinking in healthcare and to identify opportunities for improved healthcare technology. What was evident in the Lean healthcare literature was the absence of technology discussed as a tool in improvement or to aid Lean implementations with some exceptions such as exploring informatics tools with a focus on medications (Ker et al. 2014). This is in contrast to the appetite for technology in NHS healthcare strategy as a route towards improvement (Ham, 2017). This may be due to the focus on Lean tools or reflect caution in adopting healthcare technology due to sensitive nature of patient data in healthcare (Burns and Johnson, 2015). This literature gap was addressed in this thesis by expanding the literary search for the impact of technology on healthcare with a specific focus on the UK healthcare technology and recent healthcare technology studies from the USA. The selection of USA and UK was to align with the evidence that the majority of the Lean publications are from these countries (Costa et al., 2016).

Health technology thought leader cardiologist Eric Topol in his book on the "Creative destruction of healthcare" presents the use of technology in healthcare and recognises the barriers to adoption and the slowness in progress with technology (Topol, 2012). Topol highlights that technology which has resulted in the emergence of new data sources has still to be fully grasped in the healthcare delivery. He argues that

> "our health - has thus far been largely unaffected, insulated, and almost compartmentalized from this digital revolution."

This is in contrast to the way that technology has infiltrated our lives in other sectors such as retail, banking and entertainment and may reflect barriers to adoption such as ethical concerns around holding personal data (Sharon, 2017). Health Technology can however provide improvements is areas such as patient safety, clinicians productivity, reducing error, improving quality of care and increasing the patients adherence to medication regimes (Seblega et al., 2015). The healthcare technology literature does not specifically refer to Lean but Lean language such as quality and value is frequently used with discussions around attempting to understand value from the patient's perspective reflecting Lean principles within the literature (Antoñanzas et al., 2016). The removal of non-value added activities which are common Lean approaches such as waiting or medications that do not address the patient's needs are also evident in considering technology (Topol, 2012).The implications of value stream mapping and waste identification are also illustrated in Yock et al.(2015). Yock et al. (2015) explores the argument that US healthcare is not sustainable and requires redefining value from the patient perspective which would reflect the attractiveness of Lean identified in chapter 3. The rest of this chapter will explore this further by critiquing as outlined in figure 4.1.

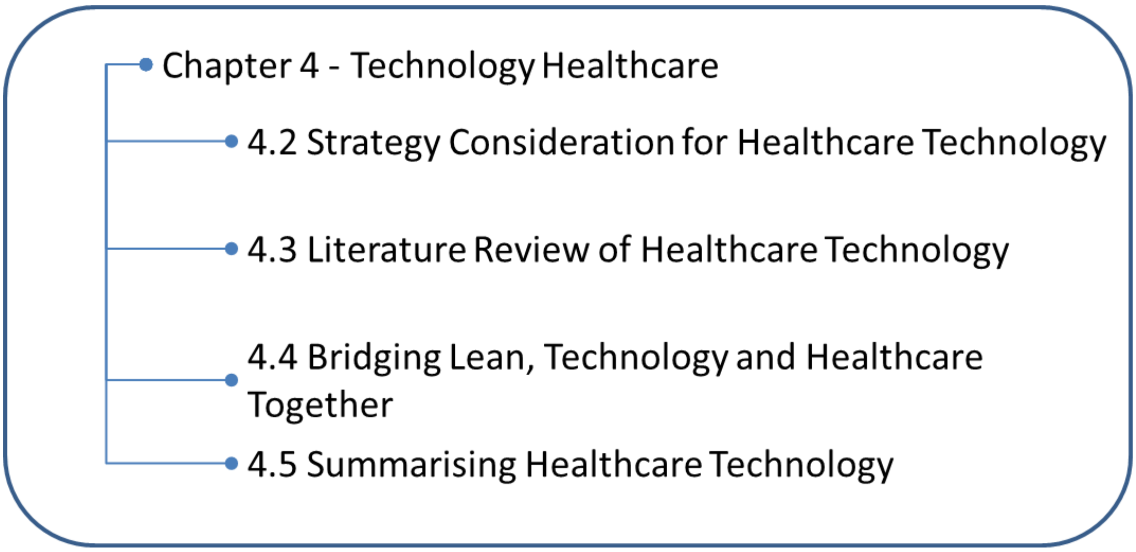


Figure 4.1 – Chapter 4 Overview

4.2 Strategy Consideration for Healthcare Technology

Government healthcare strategies represent a source for understanding technology in healthcare as deployments can be seen by policy makers as a method of addressing the healthcare crisis and addressing productivity (Jofre-Bonet and McGuire, 2014). Governments are seeking cost savings and health improvements through technology however they can struggle to achieve the benefits that other industries achieve due to the fragmented nature of healthcare and lack of interoperability (Seblega et al., 2015). They are often grappling with the reality of maintaining the current service and assessing the potential “clinical and cost advantages” of emerging research and technology (Campbell et al., 2017). The healthcare strategies also reflect a degree of political caution as they must align with the wider public appetite and ability to deliver. The Northern Ireland E-Health and Care Strategy (Department of Health, 2016) focuses on principles of citizen centred, connections, consistency, creativity and cost effectiveness but shows evidence of lots of consultation rather than leadership in defining a route to better productivity. The NHS England’s “5 Years Forward strategy” from 2014 was a significant leadership piece and continues to stimulate major debate due to identification of major funding gaps and shifts to care models needed for the future (Ham, 2017). The strategy is a call for change and emphasises the need for improvements in performance efficiency and better use of innovative technologies to address the many challenges. While the Lean terminology is not used the underlying principle of the document is that value for the patient should be redefined and this will require a move from illness interventions towards creating and maintaining healthcare that avoids illness (Stevens, 2014). Additionally the concepts of new care models reflect system thinking with the value chain focusing on the patient, not the care provider. The value chain will start outside of the hospital in the community and may cross in and out of a care facility or multiple care facilities to create patient value.

The USA are also attempting to reform healthcare with changes to healthcare under President Obama causing significant political debate and discussion (Rak and Coffin, 2013). The Patient Protection and Affordable Care Act (PPACA) and the Health Information Technology and Economics Clinical Health (HITECH) Act has driven the implementation and adoption of Electronic Health Records in the USA and stimulated interest in Technology integration with the challenges and benefits caused by adopting this (Burns and Johnson, 2015).Through these legal changes the USA Government provided a structure for changes with related funding and specific parts of the law stating that providers must be a meaningful user of the Electronic Health Records or face financial penalties. The law changes were phased to move to a point of providing more use of electronic patient portals.

In line with the focus of this thesis and the identified Lean Healthcare literature for Northern Ireland, UK and USA are outlined in 4.1.

Table 4.1 –Government Health Strategies

	Context	Focus	Linkage to Lean
Northern Ireland E-Health and Care Strategy - (Department of Health, 2016)	The strategy was launched in late 2014. This comes after a series of significant investments over the last 20 years including unique health and care numbers across the Northern Ireland population, regional electronic health record and the regional imaging system.	Supporting people, sharing information, using information and analytics, supporting change, fostering innovation and maintaining and improving what is already in place.	• Data will play a significant role in decision making by professionals across disciplines, • The linkage of data to support service efficiency • The collection and sharing of patient data enabling patients to become more

			engaged with their own care and decision making.
NHS England's Five Years Forward (NHS, 2017)	Launched in October 2014 providing a strategic overview of the challenges and needs of the English NHS. Strategy emphasises the sense of urgency and that "doing nothing" is not an option. The budget won't be available to sustain as-is and the patient needs are changing.	Prevention of disease and early intervention in the care delivery. Addressing sharp rise of avoidable illness. The need for co-creation and ownership of care by the patients. Additionally, the need to cross silos of care and address where a patient may have multiple diseases and not just one is a key message.	• Recognises care is across collection of care providers (Value Stream). • Providers in the value stream include hospitals, GP's, physical specialists, mental health specialists and social care staff. • Change in patient demands as more people living longer and often with a multiple condition, known as co-morbidities.
USA Government Initiatives	The PPACA and the HITECH acts which were initiated under President Barrack Obama and commonly referred to as Obamacare. While a significant amount of media attention is focused on providing Health	The first stage of the HITECH act focuses on Electronic Health Records (EHR) and on data collection. Stage two of the HITECH Act was to focus more on interoperability.	• Use of data and providing better data to inform decisions as the patient level seen as key. • Creation of meaningful use of data for better

	insurance access the HITECH was broken into a number of stages to direct and stimulate the adoption of technology and information exchange in healthcare. This addresses key challenges of sharing patient level data between care providers. President Donald Trump has attempted to repeal parts of these laws in 2017 and has been successful in some areas such as fines for the uninsured but large parts of the law and direction are still in force.	Every provider must have a patient portal. Stage three, was to involve the seamless exchange of healthcare information.	care. • Use of technology to link patients to care providers.

In summary, the one can see an increasing focus on technology that can collect and utilise data in new ways both at the individual patient level and the provider level. Secondly the growth of the understanding of prevention, co-morbidity and long term conditions is a common interest which is seeking new models of care. Another notable related critique is the contrast between the healthcare technology strategy work and the Lean healthcare literature. In the healthcare technology strategic direction is the centrality of patient value in the discussions compared to Lean healthcare which has the provider's activities at the centre. This patient centrality is however diluted at times by the perceived conflict of limited resources and demand outstripping supply. This particular area of understanding return on investment to justify technology costs is a potential area for Lean to assist as utilising technology to remove activities could be directed, measured and calculated within Lean in a way that technology would not identify as technology may focus on making a bad process faster where Lean will question which processes should be addressed for value in the new system. Figure 4.2 highlights the key challenges and gaps identified in healthcare technology. This will be built upon further in the next section which broadens out the literature search beyond strategies.

Summary Points for 4.1 and 4.2

Challenges

- Barrier to adopting technology in healthcare (Topol, 2012)
- Utilising Technology to support Clinical Decision Making through better information exchange (Department of Health, 2016/HITECH)
- Technology addressing Lean core areas such as quality, reducing error, productivity and process adherence (Seblega et al., 2015)
- Technology to integrate care for patients (Ham, 2017)
- Self Care, Self Management and Prevention of avoidable Illness (Ham, 2017)
- Budget Sustainability/Cost Control (Ham, 2017/PPACA)
- Addressing Ageing Population needs (Ham, 2017)

Literature Gaps

- How to engage clinicians and staff not well addressed by Technology literature
- Contrast between Lean benefits and Technology benefits not drawn out in literature.
- Patient level data collection for long term conditions not explored possible between Lean and Technology.
- Productivity and return on investment which is challenging for technology not explored with Lean approaches.

Figure 4.2 – Summary of Technology in Healthcare

4.3 Literature Review of Healthcare Technology

To progress the aims of this thesis there is a need to look beyond the strategy documents mentioned in the last section and the NHS implementations reviewed by Currie and Finnegan (2011). Peer reviewed articles on healthcare technology may provide some insight into healthcare and the use for health technology, the issues or complexities that are being dealt with in technology deployment and the types of technology that is being used. From these one can begin to see the relevance of health technology to healthcare improvement and explore potential overlaps or build on a Lean healthcare model. This could lead to a position of addressing the Lean healthcare gaps and consider models for Lean and healthcare technology to collaborate.

The literature search focused on technology literature from 2010 to 2017 with a recognition that the rate of change in technology can make older technology reviews less relevant. The search focused on peer reviewed literature and excluded technology which was not patient facing such as construction in healthcare technology or would not lead to patient improvement. The critique focused on NI, UK and USA healthcare technology literature in line with the majority of Lean Healthcare literature. Table 4.2 provides a summary of the technology healthcare literature.

Table 4.2 – Summary of Technology Healthcare Literature

Area	High Level Summary	References
Health use Case	Ageing in Place Assisted Living Technology Clinical Decision Support Unnecessary Procedures Assisted Living Technology Enhance Productivity Reduce Cost	Holliday et al. (2015), Forbes et al.(2013), Storey (2013), Spaulding et al (2013), Evans and Belansky (2013), Oderanti

	Reduce medication error Wireless vital signs Accurate billing Inventory Control Collaboration, sharing information, accessing reports, accessing results, medication and procedure history. Diabetes Evidence of billing which reduces questions from insurers Standard work Efficiency and co-ordination Evidence based medicine Decision support Ordering Rare disease Complex case support Information Sharing and Management Paperless Operations	and Li (2016), Caldeira et al. (2012), Reddy et al. (2012), Adams et al. (2011), Hung et al.(2010), Pope and Turbill (2017)
Issues and Complexities	Barriers to technology adoption in elderly people Sustainable business models for technology (*Use of technology for prevention*) Assessing Health Technology Quality Assurance Usability Adoption Developing and selling the case for change Privacy Quality Security Implementation of Electronic Medical Record (EMR) Imprecise Data for Evaluation Regulation	Antoñanzas et al. (2016), Turan and Palvia (2014), Yang et al. (2013), Vondrak (2012), Hung et al (2012) Moores (2012), Eastman and McCartney (2012), Huang (2012), Storey et al. (2011) Venkatesh et al. (2011), GOH et al. (2011), Wu et al.

	Developing Countries Electronic Health Record (EHR) return on investment Change Management issues	(2011), Currie and Finnegan (2011) Spil et al. (2011), Sugrue (2010), Parks et al. (2010)
Types of Technology	Electronic Assisted Living Technology (eALT) RFID EHR EMR AI/Decision Support picture archiving and communication system (PACS) Assistive Communication Technology (ACT) Patient Practitioner Communication Ordering medication Interoperability Medical Histories Health information Exchange Inventory Voice Recognition Software Social Media Mobile apps and services Prescribing Systems Lab Reporting Service Oriented Architectures (SOA) Business Intelligence	Mansfield-Devine (2016), Holliday et al. (2015), Ming-Tsang et al. (2013), Carlson (2013), Wamba et al. (2013), Bhakoo and Choi (2013), Storey (2013), Yang et al. (2013), Bardhan and Thouin (2013), Berger and Adedeji (2013) Johnson (2013), Kshetri (2013), Themistocleous and Morabito (2012) Geisler (2011), Smith (2011), Ferrand et al. (2010), Carr et al. (2010) Lee and Meuter (2010), McGrady et al. (2010), Söderholm and Sonnenwald (2010) Zare Mehrjerdi

	(2010), Parks et al. (2010), Pope and Turbill (2017)

While the use of technology is wide and varied there are some key themes emerging from the current technology literature which are summarised as;

1) Emerging Legislation: The use of electronic records in healthcare has largely been driven by USA government legislation (Peng et al., 2014) linked to the Obama administration. Related research then emerges which is related to the value of the health records and their interoperability.
2) Emerging technologies: The technology push continue to be part of research as products are discovered and trialled in healthcare to explore their value and usability. Examples of this include the use of data analytics (Vaughn-Cooke et al. 2015) and Artificial Intelligence (Carty, 2017)
3) Emerging challenges is an additional theme of the technology research as technology providers attempt to respond to specific challenges. This can include topics such as healthcare infections (McGukin et al., 2015), non-adherence to medication (Vaughn-Cooke et al, 2015) or security issues (Mansfield-Devine, 2016).

The contrast between Lean healthcare and technology healthcare is also relevant to the thesis and what emerges from 4.1 in the use-cases is an overlap of objectives in both areas. Areas such as unnecessary procedures, enhance productivity, and reduce cost and the reduction of medication errors is common in Lean and technology implementations. In figure 4.2 one can see there are a number of areas in healthcare technology which are beyond the scope of Lean healthcare, such as data security, and although relevant to the patient and patient value these are clearly a technology challenge which must be addressed fully. There are areas such as reducing errors which are common to Lean healthcare and healthcare technology which reflect a shared requirement. There are also areas emerging in the healthcare technology however that are Lean healthcare literature gaps. For example the challenges of an ageing population with long term conditions appears in the gaps for Lean healthcare literature however technology is addressing these challenges (Holliday et al,, 2015). In addition there are example of where Lean healthcare is addressing issues such as standard work and technology is also addressing this however Lean is not fulfilling this requirement completely and has room for improvement as many of the critiques reflect this. For example Lean faces criticism for a lack of definition (Samuel, 2013), short sighted nature of deployments (McCann, 2015) and lack of continuous improvement with capability building (Smith, 2016) which with technology could be addressed as the scale of deployments tend to be wider and standardisation across many locations is required for the technology to be a success. This is not without its challenges as buy in and adoption of technology is slow despite the major benefits (Peng et al., 2014).

While the Lean and Healthcare Technology literature has focused on USA and UK there is some notable Lean literature in Sweden where it is claimed that 9 out of 10 hospitals have some element of a Lean deployment (Dannapfelet al., 2014). Also Saskatchewan, Canada has the largest deployment of Lean which is based on the productive ward series from the UK (Sazi et al., 2017). Finally, other countries such as the Netherlands and Brazil feature in literature reviews for their deployments. Across these wider deployments is a repeated pattern of adopting tools within wards, departments and hospitals but not following the patient or considering the impact of technology on patient value. Figure 4.3 illustrate the overlaps and gaps between Lean healthcare and healthcare technology which is not discussed in the Lean literature.

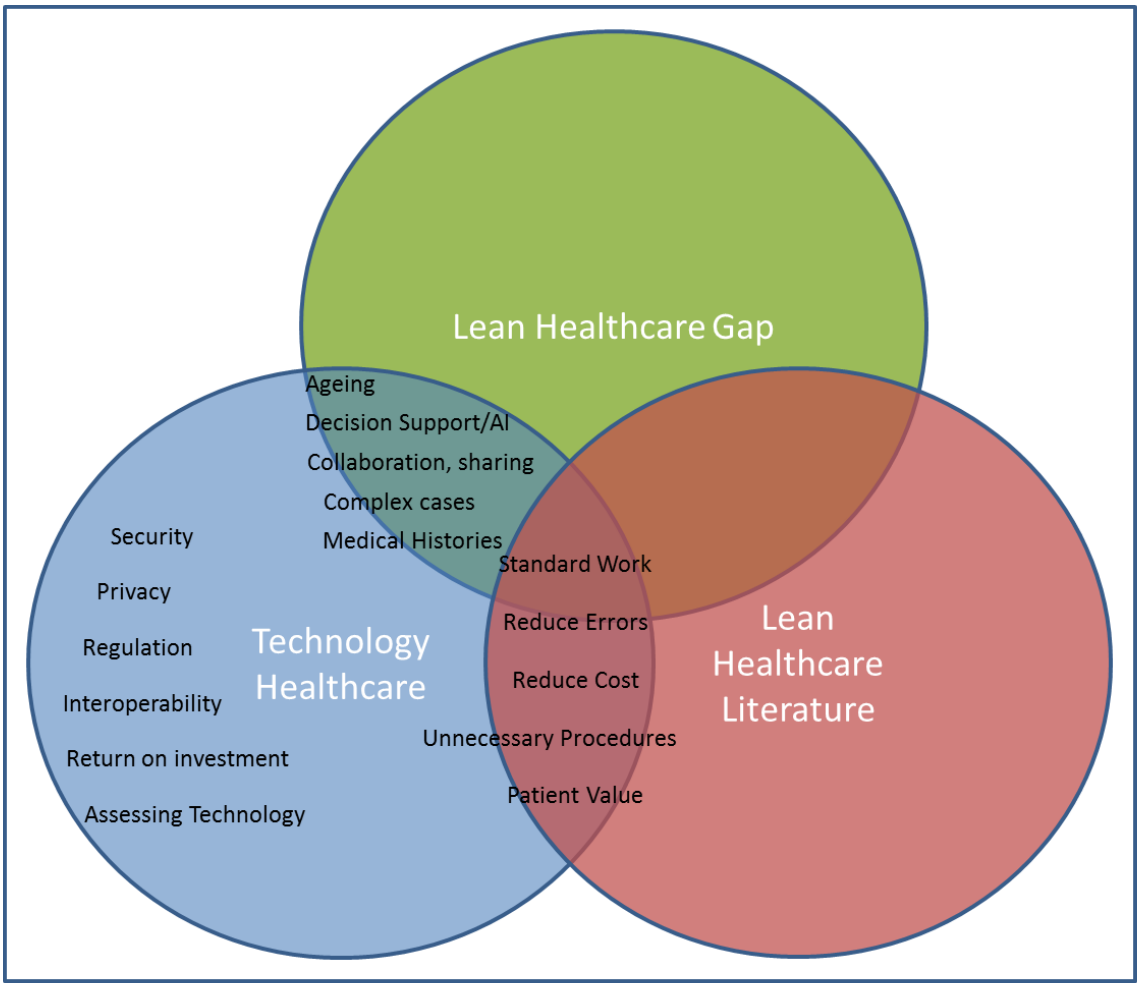


Figure 4.3 – Illustrating the Overlaps and Gaps between Lean Healthcare and Healthcare Technology

Beyond the contrast with Lean healthcare and Lean Technology a number of other points which emerge in the critique of technology healthcare literature. The volume of technology implementations are substantially higher than the Lean implementation in healthcare as most hospitals have elements of technology and many hospitals have been on technology journeys over a substantial period of time (Peng et al., 2014). Specific technology such as an Electronic Health Records, which are not available in every hospital, may impact across a whole hospital where Lean healthcare can be limited to a function such as pharmacy (Ker et al., 2014) with some minor exceptions of Lean deployments being widespread across the hospital (Mannon et al., 2014). Healthcare technology can cross organisation boundaries and silos to share data and communicate in ways that are not illustrated in Lean deployments as the focus on specific provider areas such as emergency departments or pharmacy providers. Healthcare technology focusing on data acquisition and sharing reflects the US HITEC stage three plan which focused on the “exchange of healthcare information” with the target outcome of improving care and reduce unnecessary procedures through better sharing of information. Similarly, in 4.1 one can see how technology is being used to address the sharing of information, joint working, collaborations, sharing information, accessing reports, accessing results, providing medication details and sharing patient procedure history. This need for sharing which is present in technology based reform reflects some of the areas described in the Lean criticisms and gaps such as the functional silos preventing value being achieved (Radnor and Walley, 2008). In addition the focus of technology includes long term conditions such as diabetes, rare disease and complex conditions which reflect an emerging need for healthcare to focus on conditions and identifying patient value (Porter and Lee, 2013).

Technology however can faces challenges in gaining staff “buy-in” and adoption with significant numbers of clinicians reporting to not use the technology available to them which provides issues in terms of waste but also in the collection of consistent patient information and standards in creating complete care records. Health Technology programme can suffer significantly from a lack of buy in and significant negative public backlash which is illustrated in the NHS Connecting for Health Programme which included the implementation of Electronic Health Records for 50 million citizens and absorbed an estimated £12.4bn investment billions of pounds of public money and was widely regarded as unsuccessful (Currie and Finnegan, 2011). The Currie and Finnegan (2011) seven year study suggests that forcing change on healthcare professionals and barriers such as cultural norms, values and behaviour patterns significantly slowed progress. However the complexity of the problems makes it difficult to draw specific conclusions. The research recognises the need for technology not to be viewed in isolation from the organisation but must become embedded. This area of buy in and evidence is an area where Lean healthcare has some advantages as the processes of Lean can build the evidence base of improvement (Burgess and Radnor, 2012) that may be necessary for technology adoption.

Patient buy in to health technology can also be difficult as evidenced in the English NHS “care.data” programme as negative patient data and privacy issues attracted widespread negative media attention and patients distrust (Carter et al., 2015). This Carer et al. (2015) paper highlights that technology use in the health service and specifically the use of data can struggle in both data protection issues and also in perceived data management or ethics issues where the public is putting a level of trust in health systems. This issue is summed up in the BBC headlines “Care.Data: How did it go so wrong?” as the article summarises a difficult change programme which had attracted the condemnation of the British Medical Association, privacy campaign group Big Brother Watch and Medical Research Charities (Triggle,2014). Patient buy in can also be difficult for new technology as patients may struggle to understand the technology, may not trust it and may be scared of it (Kayyali et al., 2017). Additionally gaining sufficient evidence for approval of medical devices can be problematic and result in significant numbers of technologies being rejected and evidence of the patient benefits can result in medical devices being rejected (Campbell et al., 2017).

In summary, one can see overlaps between technology and Lean implementations with strengths in technology of wider adoption and identification of data that may assist in improving care. Lean strengths of adoption may be valuable for Technology which struggles with adoption.

4.4 Bridging Lean, Technology and Healthcare Together

While this thesis has been critical of the lack of technology present in Lean Healthcare there have been some references to better use of “information flow” through the use of systems (Umachandran, 2016), reference to the implementation of prescribing systems that use Lean methods (Ker et al., 2014) and targeting of the “technology enabled” groups as having potential for Lean deployments (Hwang et al., 2014). Additionally, although not specifically focused on healthcare Riezebos and Klingenberg’s (2009) article discusses the changing role of technology and emphasises the need to recognise Lean’s background being routed in scientific management and the potential role for technology within Lean deployments. These small bridges between health, Lean and technology appear to reflect a natural join on the collection and use of data to create evidence for decision making. Advances in technology mean that the data available from modern IT systems can provide the ability to support decision by patients, clinicians and researchers which can lead to more patient participation and personalising care (Sharon, 2017). This need for significant data to make decisions is reflected in many Lean healthcare deployments such as the Bolton NHS deployments which make makes reference to the Lean PDSA cycles which were supported by data alongside rapid improvement events (Bowerman and Fillingham, 2007).

The small number of Lean healthcare technology overlaps point toward the emergence of new technology that can focus on patient needs or value through the acquisition of better data which is appropriately shared. An emerging position for Lean healthcare technology is to focus on technology related to data acquisition and use. This would support the understanding that Lean is built on the principles of decisions being made and tested based on data (Riezebos and Klingenberg’s, 2009). Topol (2012) supports and extends this view by agreeing that data analytics will begin to change how healthcare will be delivered. With some transfer from Riezabos and Klingenber's (2009) findings to healthcare one can infer that technology sourced data can bring us closer to that scientific data which in the hands of health managers and clinical decision makers could provide significant decision making tools to address waste and provide improvements in the ability to address patient value across more complete patient value chains. This position which connects technology data to Lean improvements can be triangulated against healthcare technology where cost improvement are associated to the use of Electronic Health Record adoption leading to cost reductions (Shen et al., 2015). Figure 4.4 below provides and overview of the main learning points from section 4.3 and 4.4.

Summary Points for 4.3 and 4.4

Challenges

- Lean could benefit for the use of large data sets for evidence building and decision making (Riezebos and Klingenberg's, 2009)
- Overlap of goals between healthcare technology and Lean application is evident in areas such as unnecessary procedures; enhance productivity, reduced cost and the reduction of medication errors
- Big data could sit alongside RIE events (Bowerman and Fillingham, 2007).
- Technology used to address emerging long term conditions (Holiday et al., 2015) & (Porter and Lee, 2013)

Literature Gaps

- Further opportunities are available to address Lean healthcare gaps in Collaboration, sharing information, accessing reports, accessing results, medication and procedure history.
- Methods of addressing the technology failures for staff to adopt technology (Currie and Finnegan, 2011)
- Methods of addressing the data sharing challenges of technology (Carter et al., 2015).

Figure 4.4 – Summary Diagram 4.3 and 4.4

4.5 Summarising Healthcare Technology

To summarise the view of healthcare technology one must return to the purpose of the thesis as one seeks to identify opportunities for improved healthcare technology the following are clear;

- A large overlap between the value created by healthcare technology and Lean.
- Emerging desire for better use of data within healthcare systems
- An emerging need to address long term conditions in technology healthcare.

The first point about an overlap of goals between healthcare technology and Lean application is evident in areas such as unnecessary procedures; enhance productivity, reduced cost and the reduction of medication errors. Further opportunities are available to address Lean healthcare gaps in Collaboration, sharing information, accessing reports, accessing results, medication and procedure history. The second point on better data reflects technology advancement where more data is being created by more systems, devices and citizen centric social media. Global healthcare providers have an interest in the use of technology to address healthcare challenges at a scale of deployment and sustainability that Lean is unable to reach. The final point is on the opportunity to address better care for long term conditions. This reflects an emerging opportunity for improvement that has not been fully explored in Lean. Utilising new technology to gather data could provide new models of lean healthcare addressing patient value for Long Term Conditions. Technology advances in particular could address emerging challenges in understanding long term conditions such as Diabetes, rare disease and complex conditions which span between different clinical disciplines and facilities. This reflects points raised by Porter and Lee (2013) about focusing on specific health conditions and identifying values that are currently not measured or addressed.

To bring Technology, Lean and Long Term Condition focus together will require a modification to existing models of implementing Lean in healthcare. This brings us to the next section of considering the learning and theoretical development to guide the empirical part of the study.

Chapter 5 – Theoretical Development of the role of Lean thinking in integrated healthcare patient pathway reform to identify opportunities for improved healthcare technology

5.1 Introduction

The aim of the thesis presented in chapter 1 is to explore the role of Lean thinking in integrated healthcare patient pathway reform to identify opportunities for improved healthcare technology. This thesis seeks to consider the question of originality and utility to provide a theoretical contribution to knowledge and a contribution for practitioners considering healthcare reform (Corley and Gioia, 2011). To achieve the initial objectives from the research, the literature reviews have focused on Lean in public services and Lean in healthcare to reflect the nature of healthcare being a public service in the UK. The literature revealed a lack of reference to technology which therefore required a review of literature and strategy documents focused on technology in healthcare. Jointly the critical analysis of Lean related theory in healthcare reform and the use of technology within healthcare reform were completed to achieve objective one of the thesis and move towards a theoretical framework to guide empirical analysis in line with objective 2 prior to addressing objectives 3 & 4. This chapter and chapter 6 will focus on theoretical development and methodology in order to position the thesis to meet objectives 3 & 4 which focus on investigating emerging technology to address improvement areas identified (objective 3) and explore the development of a theoretical framework for Lean healthcare technology models which utilises the learning and approaches of Lean and opportunities presented by technology (objective 4). A summary of the chapter 5 headings is provided in figure 5.1.

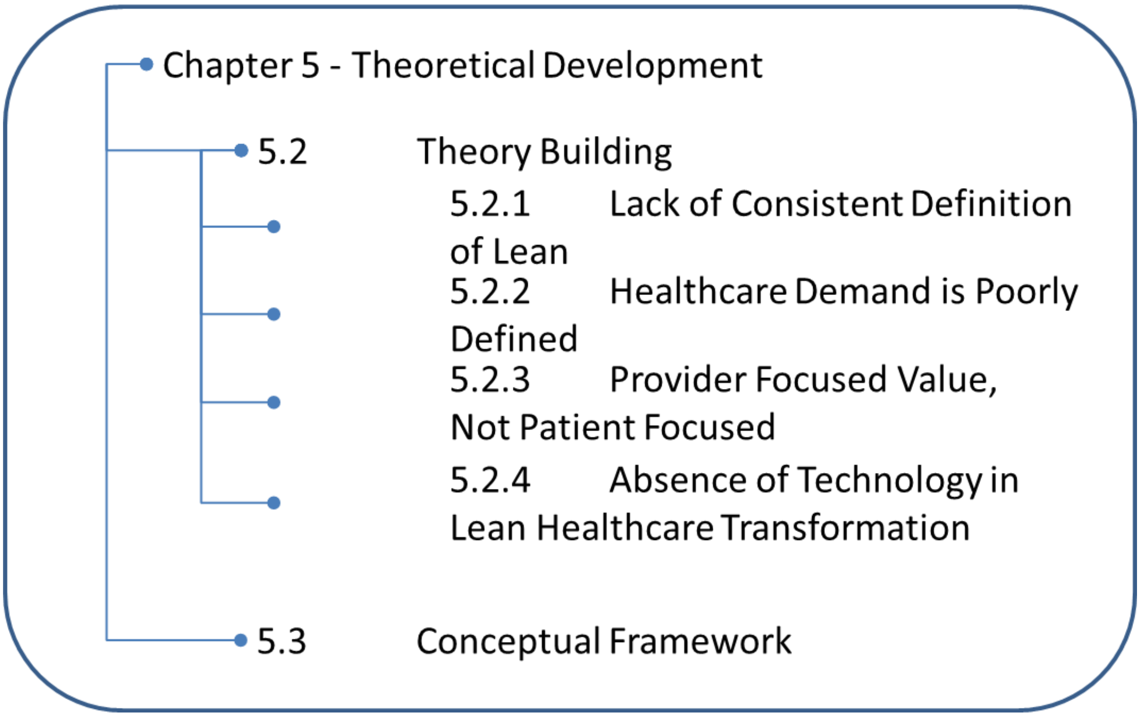


Figure 5.1 – Chapter 5 Overview

5.2 Theory building

The review of the literature that has been discussed in the previous chapters has led to a number of conclusions that will be discussed below before being brought together into a framework for the gathering of empirical evidence.

5.2.1 Lack of Consistent Definition of Lean

The lack of consistent definition of Lean is a frequent challenge throughout the literature and is highlighted by Samuel et al. (2015) by describing the different “discourses” of Lean. While this pragmatic approach may have some advantages in allowing Lean to be adapted to various approaches and people groups this has created distinct challenges (Young and McClean, 2007). The lack of consistency means that interventions can’t be sufficiently measured and this will lead to a lack of quality evidence (Antony et al., 2016) making it difficult to measure the improvement and the level of success or failure attributed to its implementation. This is reflected in criticism of Lean in healthcare Moraros et al. (2015) where comparisons between lean implementation were assumed to be the same yet there was no consistent definition of what a Lean implementation was. This is reinforced by Samuel et al. (2015) who codified the different approaches to Lean and highlighted that the practitioner view of Lean was different things for difference people. Extending this criticism further the issue of continuous improvement is often absent as a poor definition of what Lean is? leads to an inability to gather evidence of improvement and therefore leads to reduced ability to improve the approach. This can be due to the short term nature of many deployments seeking “quick wins” or service improvement (McCann et al., 2015) without understanding the implication of Lean “Perfection” principles.

5.2.2 Healthcare Demand is Poorly Defined

There is limited challenge in healthcare about what real healthcare demand is versus presenting demand. This is due to the focus on the individual activities rather than the purpose of the system. Error and quality failure are clearly evident in healthcare delivery and leading to a demand in the system as activities are generated to address value not met elsewhere (de Souza, 2009) such as A&E visits due to the preventative activities not being addressed by the GP or the patient. By placing the provider as the centre of Lean the assumption is that all that engagements with the patient is going to lead to value creation which may not be true as the patient may be there due to previous failure in the system (Porter, 2013). This ill-defined demand or failure demand (Seddon, 2008) is not adequately explored in Lean healthcare literature as shown in chapter 3.

5.2.3 Provider Focused Value Not Patient Focused

The first of the Lean principles as defined by Womack et al. (1991) has defining value for the customer as the primary objective and from this the value stream of activities necessary and other principles of Lean are applied. The definition of Lean in healthcare however starts with the context of the provider and attempts to define Lean value in relation to the lab, operating theatre, hospital or clinic. Value is limited to a provider focus with the care activities being addressed for flow rather than value for the patient. Despite the growth in Long Term Conditions from an ageing population (Dannapfel et al., 2014), the application of Lean continues to be limited due to the focus on care providers not patients. Patients increasingly have a number of health conditions and will therefore be sent to a selection of specialists who have silos of care without understanding value for the patient. Essentially they are treating symptoms or a condition not a patient and Lean healthcare approaches reinforce this by applying Lean to the provider’s silo. There are limited case studies or applications of Lean healthcare applications that go beyond an individual care provider or specialty.

5.2.4 Absence of Technology in Lean Healthcare Transformation

Healthcare technology application was largely absent from Lean healthcare literature despite the interest from provider in the use of technology to address unmet needs in healthcare (Ham, 2017). Healthcare technology literature shows early evidence of addressing the health outcomes of working in ageing populations with Long Term Conditions and extending them to address value outside the hospital which could provide opportunities for Lean (Holliday et al.,2015). Healthcare technology is being used to promote information sharing through data gathering, sharing and analysis technology which is of particular relevance to addressing wastes identified in Lean healthcare and promoting a Lean scientific management approach suitable for continuous improvement. Staff engagement is also a key issue with Lean healthcare (White et al., 2017) which can be clearly evidenced in the use of technology as clinicians and healthcare workers utilise technology as a core part of their role. There is potential of the engagement seen in technology to provide a consistency in approach often lacking from Lean (Young and McClean, 2007) which could improve outcomes for patients.

Based on these points from the previous literature analysis chapters, the research gaps outlined in figure 5.2 have emerged as a theoretical framework that recognises the literature outputs, the emerging gaps, the unrealised technology opportunity and the emerging healthcare trends.

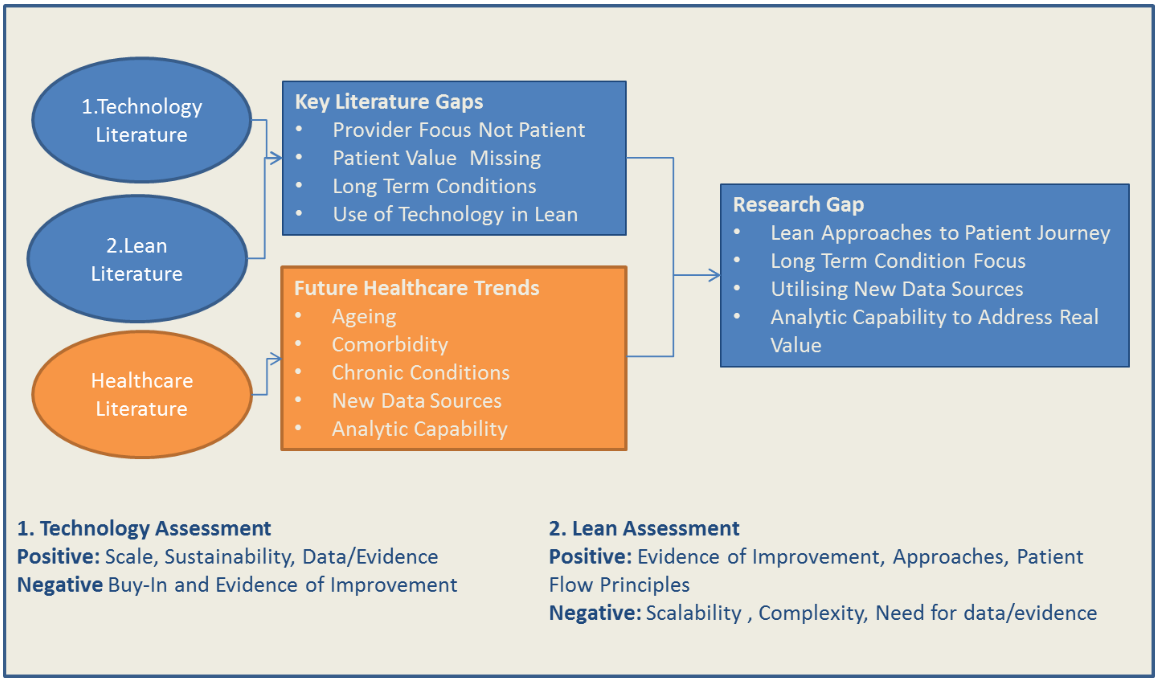


Figure 5.2 –Key Gaps and Trends in Technology, Lean and Healthcare

In addition to the literature gaps reflected in figure 5.2, a series of key Lean wastes from Lean healthcare literature have been identified to assist in developing a theoretical framework which could be applied to empirical evidence. The development of this initial Lean healthcare wastes framework for long term conditions in itself is a contribution to theoretical knowledge that has value academically and to practitioners. The use and further development of this would assist in addressing objective 3 and 4 by investigating emerging technology to address improvement areas and exploring the development of a theoretical framework for Lean healthcare technology. The Lean healthcare wastes identified in healthcare (Chapter 3) are documented in 5.1.

Table 5.1 – Consolidated Lean Healthcare Wastes from Healthcare Literature

Healthcare Failure Area Identified in Chapter 3	*Description*
Waiting times	*Awaiting treatment to begin*
Delays	*Waiting for activities, results while being treated*
Activity Transaction Speed	*Related to activities within the value stream*
Diagnostic	*Turn-around times*
Medical Complexity	*Increasing strokes risks and amputations*
Additional Healthcare Visits	*Follow up, review or further appointments than necessary*
Co-ordination of Healthcare resources	*Often lack of coordination producing additional activities*
Stress/overload of staff	*Often driven by lack of clarity and inefficient processes*
Repeated Procedures	*Missing test result, records or updates requiring repeated work*
Motion/Transport	*Including staff walking*
Length of Stay	*Average length of stay is a key measure of hospital performance but needs to be balanced with readmission rates*
Cost	*Wasted money and processing additional claims or costs*
Quality	*Errors in practice or administration of care*
Emergency Admissions	*Unplanned, avoidable admissions regarded as a failure in the system. For example an escalation in a condition which could have been prevented*
Death	*Unnecessary mortality due to falls, infections, Turn-around times*
Medication errors	*Wrong drug, dosage or administration*
Infections	*Caused by the medical interventions or environment of medical intervention*

Emerging from this research and not covered in Lean Healthcare Literature	*In each of the sections there will be a final row to highlight waste and non-value add activities that have been identified in the analysis which were not included in Lean healthcare Literature from Chapter 3. This will assist in addressing research question 1about how Lean can be adapted from Long Term Conditions.*

In summary, the literature gaps identified in previous chapters along with the Lean wastes identified throughout the literature critiques provide key areas to build a conceptual framework to apply to develop further empirical research. Healthcare literature has identified emerging trends in patient needs with Long Term Conditions being a key focus due to crossing the institutional silos. Healthcare technology provides opportunities to cross the silos and identify opportunities to address waste and improve healthcare delivery. These are explored in the conceptual framework in the next section.

5.3 Theoretical Framework

What is clear is that a literature gap emerges from Lean healthcare literature and healthcare technology literature where the value stream for a long term condition patient who cross a number of care providers is not addressed and the opportunities presented by healthcare technology are not considered. Lean healthcare literature presents a series of wastes which have been discovered in the Lean deployments. Although these focused on specific healthcare providers, rather than the patient, they provide insight on wastes within the healthcare system. To address these gaps and utilise the emerging Lean literature findings the thesis will identify a patient value stream for a long term condition patient that crosses the various healthcare providers to identify the wastes and non-value add activities. The analysis will utilise the Lean wastes framework identified in 5.1 and specifically look for evidence of these across the long term condition value stream defined in this thesis to explore new wastes not represented by this framework. In addition a technology assessment will also be applied across the long term condition value stream to identify opportunities for technology to address waste which is present for patients. This emerging theoretical model is illustrated in figure 5.3 with a Long Term Condition Value Stream to be defined from this research. A technology focus and Lean focus for the analysed literature alongside targeted research into a long term condition will reveal a new theoretical framework for Lean Healthcare Technology Models.

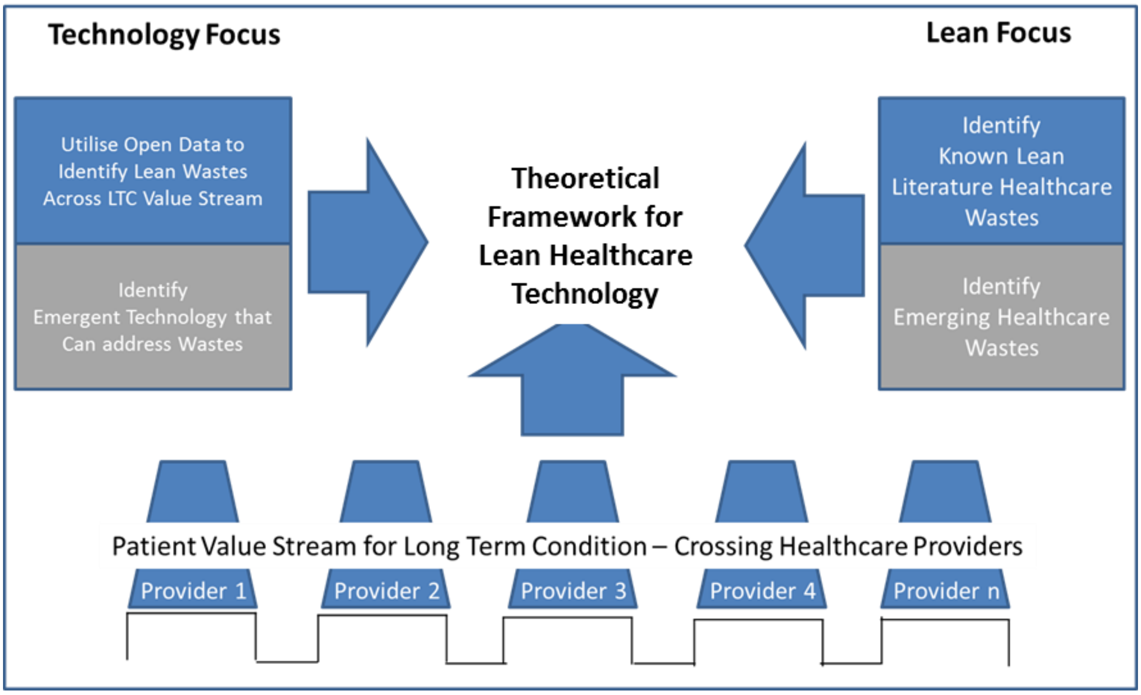


Figure 5.3 - Theoretical Framework for Lean Healthcare Technology Models

From the theoretical model the following research questions emerge to be addressed in the remainder of the thesis. The literature review of Lean in healthcare has revealed a focus on care providers and departments rather than specifically on patients (White et al., 2017). This is often for specialties and may not deal with the value for the patient. Healthcare demand however is increasing for an ageing population group with comorbidities requiring a much wider view of patient value (Dannapfel et al., 2014). To address this gap, research question one has been developed to consider the implication of an ageing population with long term conditions. Specifically, how can Lean be adapted for long term conditions?

Secondly, there is a research gap in the use of technology within Lean deployments. This is despite the technology language of value, evidence and improvement being a shared goal between Lean and technology innovation (Holiday et al., 2015). In addition the use of data focused technology to identify waste and build evidence needed for visual management and Lean decisions are a synergy that is appropriate to this research (Bowerman and Fillingham, 2007). For this reason the second research question explores if healthcare technology from data focused technology; assist in redefining patient value?

Finally, in developing the third research questions there was an interest in considering how technology can address the gaps in healthcare delivery emerging from the literature around addressing non-value add activities. Technology research had revealed that issues emerging in long term conditions can be addressed with technology and there was opportunity to if Lean and technology could address non-value add activities which are evidence in current healthcare provision (Porter and Lee, 2013). The third research question asks if health technology can assist in identifying and addressing Lean non-value add activities.

To summarise, the three research questions to be addressed are;

- RQ1 - How can Lean be adapted for Long Term Conditions?
- RQ2 – How can healthcare technology from data focused technology; assist in redefining patient value?
- RQ3 - Can health technology assist in identifying and addressing Lean non-value add activities?

These will be taken forward in the next section with a review of the research methodology.

Chapter 6 – Research Methodology

6.1 Introduction

This chapter outlines the research methodology adopted and explains the choices that were made to further the aims, objectives and research questions of the thesis. It also details the types of data analysed and the methods that were used to obtain data to address the research objectives and questions. The research design recognises the need for a research philosophy, explaining the methodological choice, strategies and time horizon (Saunders and Tosey, 2013) before explaining factors around validity, reliability and limitations. Finally, the chapter will explore the research generalisability. Figure 6.1 provides an overview of the structure of the chapter.

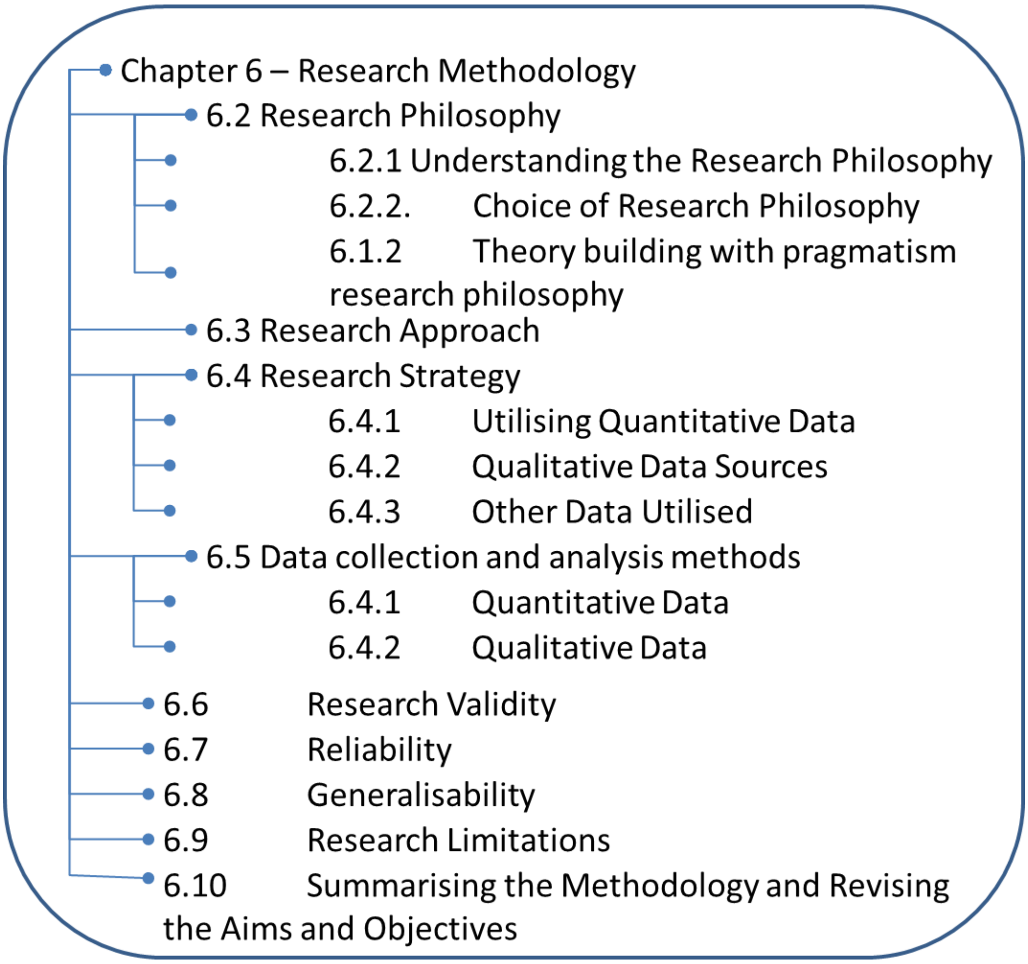


Figure 6.1 – Chapter 6 Overview

6.2 Research Philosophy

6.2.1 Understanding the Research Philosophy

For research to be successful, an appropriate paradigm should be selected as this will influence what data the researcher will see as important and useful (Saunders and Tosey, 2013). Key research methodologies include Positivism, Interpretivist and Pragmatism (Patel, 2015). Positivism is useful to "propose and test theories with data which are highly structured and usually measureable" (Saunders and Tosey, 2013, 58). Interpretivisim focuses on research related to social value and people in their natural environment with the research being "value bound" (Saunders and Tosey, 2013). Pragmatism is often referred to as a research design which will help to seek out reliable and relevant data that will support future actions with "the importance is in the findings practical consequences" (Saunders and Tosey, 2013, 58). The adoption of one of these methodologies will reflect the researchers view and also the methods of using data and the types of data. Table 6.1 highlights a comparison between these main methodologies; drawing out the ontology, epistemology, theoretical perspective, methodology and method for each of the paradigms. This has been adapted from Patel (2015) to highlight the main methodologies.

Table 6.1 – Research Methodologies Comparison – Adapted from Patel (2015)

Paridigm	**Ontology** ***What is reality?***	**Epistemology** ***How can I know reality?***	**Theoretical Perspective** ***Which approach do you use to know something?***	**Methodology** ***How do you go about finding out?***	**Method** ***What techniques do you use to find out?***
Positivism	There is a single reality	Reality can be	Positivism Post-positivism	Experimental research	Usually quantitativ

	or truth (more realist)	measured and hence the focus is on reliable and valid tools to obtain that		Survey research	e, could include: Sampling Measurement and scaling Statistical analysis Questionnaire Focus group Interview
Constructivist/ Interpretive	There is no single reality or truth. Reality is created by individuals in groups (less realist)	Therefore, reality needs to be interpreted. It is used to discover the underlying meanind of events and activities.	Interpretivism (reality needs to be interpreted) - Phenomenology - Symbolic interactionism - Hermeneutics Critical Inquiry Feminism	Ethnography Grounded Theory Phenomenology research Heuristic inquiry Action research Discourse Feminist Standpoint research etc.	Usually qualitative, could include qualitative interview Observation Participant Non-participant Case Study Life history Narrative Theme identification etc.
Pragmatism	Reality is	The best	Deweyan	Mixed	Combinati

(Patel, 2015)	constantly renegotiated, debated, interpreted in light of its usefulness in new unpredictible situations.	methos is one that solves problems. Finding out is the means, change is the underlying aim.	pragmatism. Research through design.	Methods design based research action research	on of any of the above and more, such as data mining expert review, useability testing, physical prototype.

6.2.2 Choice of Research Philosophy

Following a review of the various approaches it was possible to narrow identify the suitable approaches required to provide successful research to meet the aims and objectives of the thesis. The Saunders and Tosey (2013) research 'Onion' diagram provided a useful model to reflect the different elements from the philosophical approach through to data collection methods. This is reflected in figure 6.2.

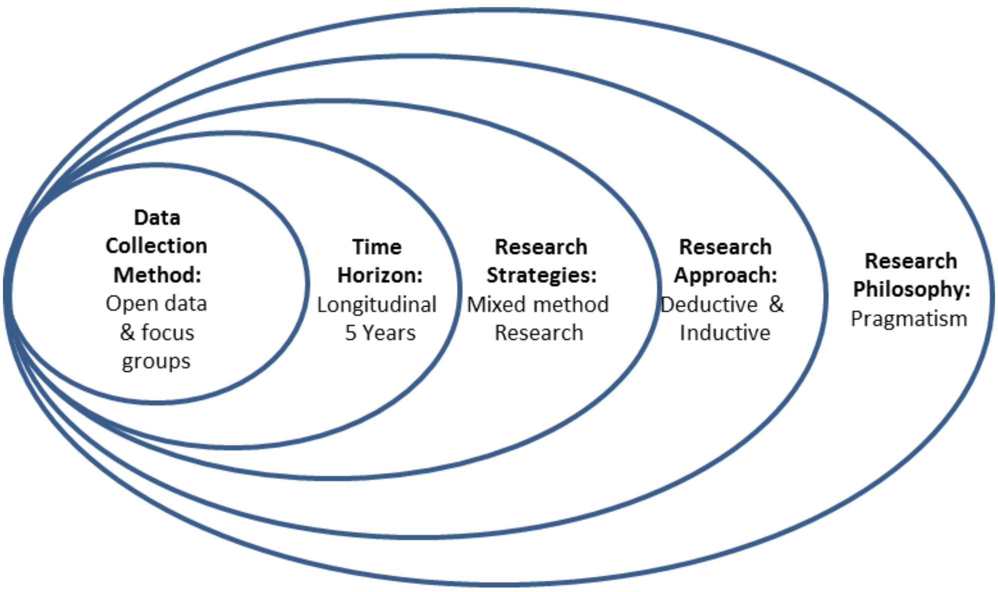


Figure 6.2 –Research Methodology Diagram based on Saunders Research Onion

From the various available approaches, the research philosophy of pragmatism was selected for the study. Positivism had some appeal due to the desire to look at quantitative data and produce finding that were based on data; however the position of a single reality was not possible when exploring Lean healthcare value which led to this being rejected as a research philosophy (Patel, 2015). Patient value can also be difficult to measure as this is evolving as life expectancy increases (Dannapfel et al., 2014). Interpretivisim was not deemed to be suited to the thesis as the research had no concern for protecting or understanding the research as research subjects but understanding and exploring the actions that will lead to a future improved results for patients in a more outcomes based approach (Patel, 2015). The understanding of outcomes was of interest to the thesis and whether the presence or absence of alternative actions would lead to positive or negative outcomes which create value in healthcare (Porter, 2010).

Pragmatism provided a more suitable philosophy for the research as findings which lead to practical consequences reflects the Lean approach (Mannon et al., 2014)). The reality of what “value” is for a patient is constantly evolving as evidence and explorations reveal new medical discoveries about treatment and therapy therefore a pragmatism approach research leads to practical consequences which fits well with the changing healthcare environment which (White et al. 2017) Healthcare demand is also “changing” as an ageing population creates a new reality with different care needs (Dannapfel et al., 2014). Lean healthcare has not discovered or removed many of the Lean wastes as it has focused on providers and not patients. The pragmatism selection is an appropriate methodology for adopting of longitudinal analysis learning approach and using both quantitative data and qualitative data (Patel, 2015). The originality and value that the thesis seeks to bring is for practical insights that will result in new applications of Lean, therefore uses mixed method provides an opportunity to explore the data from a number of angles. With mixed methods being known as a positive contribution to research as a way of "triangulation" of research, it allows for a stronger understanding and support for any relevant findings (Jogulu and Pansiri, 2011).

Pragmatism provides an opportunity to discover problems and assist in developing potential solutions which utilise qualitative and quantitative approaches which are consistent with the thesis aim, objectives and research questions:

- Big data mining that will reflect changes in demand and service provision over a time period.
- Ability to identify Lean wastes in the system and requirement to uncover where there is opportunity to address waste.
- Ability to create theoretical models and data models to assist expert reviewers in identifying healthcare wastes.
- Methods of identifying emerging opportunities in technology that could identify or address waste within the healthcare system and become part of a future lean healthcare model.

6.2.2 Theory building with pragmatism research philosophy

The research within this thesis developed with a pragmatism research philosophy seeks to conduct exploratory theory building to develop a theoretical framework for Lean healthcare technology models. To achieve this goal the research utilises the learning and approaches of Lean and seeks to understand opportunities presented by technology to improve Lean as a management approach and identify opportunities for technology to deliver better value for patients. The research was concerned with the cause and impact of various Lean health interventions and the effect they have on achieving patient value but also on understanding the views and opinions of patient facing staff that are well positioned to understand the implications of change thus requiring both qualitative and quantitative data. The selection of the pragmatism research philosophy reflects the methodology of Lean with the origins of Lean being linked to empirical evidence comparing production quality and quantity levels but also utilising frequent RIE events and guiding the view of reality (Samuel et al., 2015). While some Lean literature has focused on qualitative aspects such as understanding staff engagement (White et al. 2017) or classifying Lean healthcare (Costa et al., 2016) there is also a need for healthcare technology to justify its cost value in health technology assessments before being adopted (Antoñanzas et al., 2016) which benefits from a quantitative analysis therefore Lean must continually seek an evolving view of reality and utilise data from both qualitative and quantitative sources for theory building as new services are introduce to healthcare (García-Soleto et al. ,2013). This thesis will focus on theory building and will utilise research questions and results to develop theory as suggested by Yin (2011). This combined use of qualitative and quantitative data will require both deductive and inductive reasoning as has been utilised in hospital at home studies (Mendoza et al., 2009), From quantitative big data sets, key findings will be deduced in a deductive reasoning approach where the findings will be in the form of data representations and trends. These key finding will then be subject to qualitative enquiry (e.g. based on interviews and focus groups) inductive theory building using inductive reasoning in interpreting the quantitative and qualitative findings and representing them within an overall narrative as utilised in technology and healthcare assessments (Patel et al., 2008). Future research may benefit from theory testing, which will be discussed further in chapter 10. The research philosophy is illustrated further in 6.2 by revisiting the Patel (2015) and extending the view of Pragmatism to this thesis topic area.

Table 6.2 – Research Methodologies Adaption for this Thesis – Adapted from Patel (2015)

Paridigm	Ontology *What is reality?*	Epistemology *How can I know reality?*	Theoretical Perspective *Which approach do you use to know something?*	Methodology *How do you go about finding out?*	Method *What techniques do you use to find out?*
Pragmatism (Patel, 2015)	Reality is constantly renegotiated, debated, interpreted in light of its usefulness in new unpredictible situations.	The best methos is one that solves problems. Finding out is the means, change is the underlying aim.	Deweyan pragmatism. Research through design.	Mixed Methods design based research action research	Combination of any of the above and more, such as data mining expert review, useability testing, physical prototype.
Pramatism in this Thesis	Healthcare in a constant state of change. Thesis gap that Lean application is not addressing change. Lean and technology may be interpreted to	There is a requirement for a research method that discovers waste and value in current provision to assist in developing potential solutions.	Pragmatism allows for the emperical evidence through the data and insight from practical application within healthcare.	Mixed methods research allows the thesis to develop insights and learning from a number of sources to provide a more complete understanding.	Statiscal analysis of volumes and trends, theme analysis, case study, user group expertise interviews and opinion analysis.

	to address changing requirements.

6.3 Research Approach

The thesis adopts a pragmatism research philosophy which supports the use of mixed quantitative and qualitative data and a combination of both inductive and deductive research reasoning. Quantitative research focuses on the use of objective measures from statistics, mathematics, data collection, questionnaires and surveys utilising various statistical techniques (Patterson et al., 2014). Healthcare has a vast volume of data that has been collected over a number of years that provides an array of options for quantitative analysis. The qualitative research seeks to understand the underlying reasons for actions and driver for behaviours to assist in exploratory theory building (Greene, 2012). Due to healthcare being influenced by many stakeholders and delivered by a large number of staff from various organisations it is important to understand opinions and behaviours that may lead to actions (White et al., 2017).

From the quantitative data, the research utilises deductive reasoning to identify key findings from the analysis in relation to data trends and comparisons. These deduced key findings were then presented to focus groups and expert leaders to gather qualitative data which used inductive reasoning to further build understanding through social exchange leading to a theoretical framework for the future use of Lean in healthcare and opportunities for technology. The reason for choosing a mixed methodology with a combination of both inductive and deductive research reasoning was the importance of utilising the right sources and combination of data to lead to findings that would support future (Jogulu and Pansiri, 2011).

6.4 Research strategy

The research utilised a mixed method design that would require healthcare and technology data from a number of different sources. The research flow diagram illustrated in figure 6.2 shows how the literature review led through to the quantitative data gathering using open source big data and analysis of this data. Figure 6.2 also shows how the qualitative data was used in reviewing and interpreting the quantitative data findings to further build theory. The theory building also utilised evidence from grey literature, operational procedure information and technology horizon scanning.

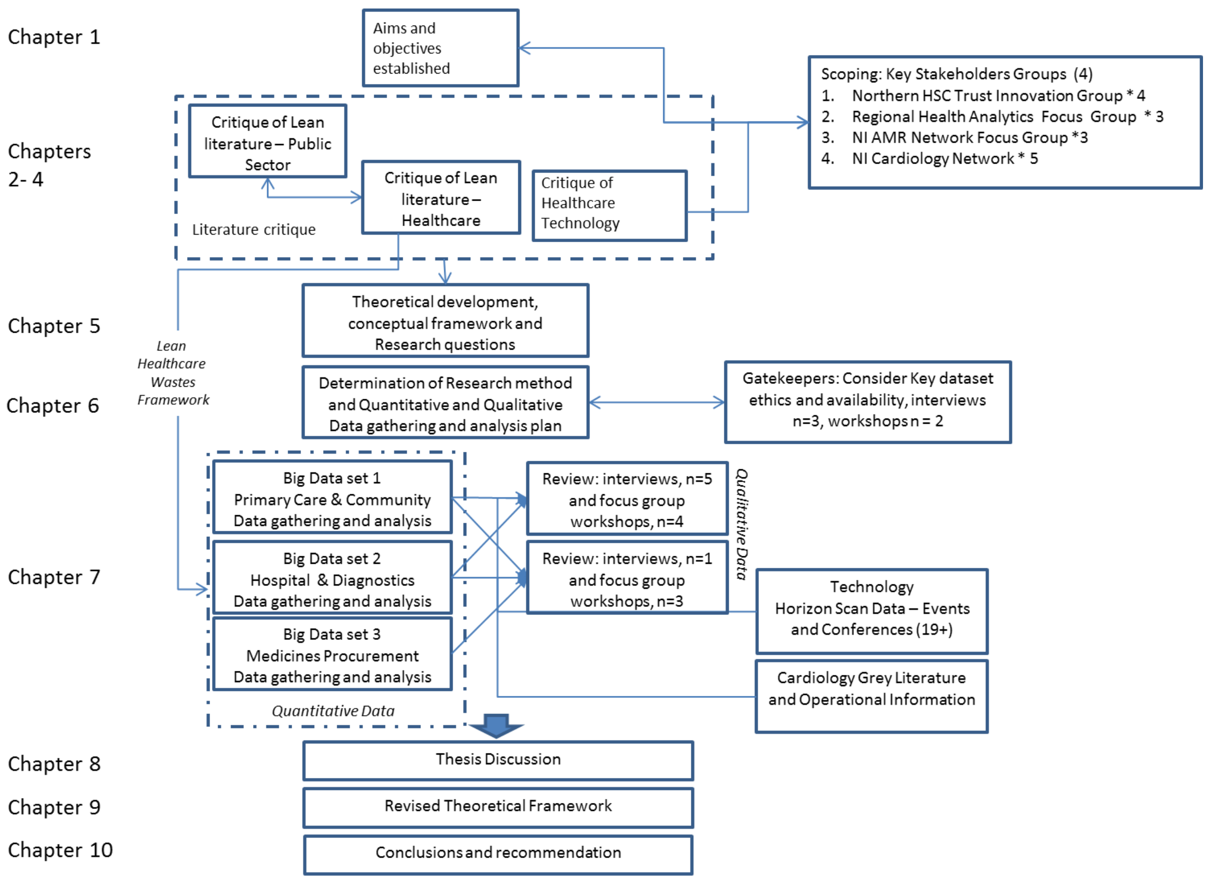


Figure 6.3 - Research Flow Diagram

There was a need for significant ethical consideration in the study and a number of decisions were made in consideration of the ethical issue and related to this the availability of data to allow for the research to be completed. During the thesis an exploration was made about introducing anonymised and pseduo-anonymised data from a service in Northern Ireland called the regional Honest Broker Service (BSO, 2018). The service was launched in June of 2014 and provides joined big data sets across the hospitals in Northern Ireland and also into a number of the community healthcare data sets. The thesis author was involved in one of the early applications to the service for a dataset for a small patient group of children with a congenital heart disease. The process of completing all the ethics applications necessary to gain access to data in partnership with a cardiologist revealed that gaining access to this data for the purposes of the thesis was not possible. The process includes university filter committees, health trust ethics committee's and national ethics (IRAS) linked to the NHS. Aside from the issues of the timescales and extensive volume of forms the ethics process requires clearly defined outcomes for the data rather than exploring the relationships and attempting to identify unusual patterns. It would not be possible to gain ethics approval for a Lean exploratory study using patient data. For this reason the focus remained on open data sets which provide completely anonymised data. While the data is immediately available and there is no requirement for ethical approval. There are some limitations, such as the ability to cross correlate between patient activities, but they allow freedom to explore data. This idea of data access being a key consideration in the research is highlighted in the research methodology flow diagram of figure 6.3 with the "Gatekeepers" role in the diagram. A summary of quantitative data challenges are listed in figure 6.4. These are limitations of the research and it would be possible for future research which is less exploratory in nature to test theories with specific data sets following an ethics application.

6.4.1 Utilising Quantitative Data

The quantitative data was sourced from healthcare providers, public health agencies and public open data providers. This data is from big data sets that have been collected for statutory reporting and operational improvement purposes however the processing completed for the thesis and use of the data reveals new insights beyond the initial data collection, consistent with big data analysis rationale (Dominic et al., 2015).

The selection of the appropriate data was informed by a pragmatism research philosophy with the data gathering focused on cardiovascular disease patients. The use of cardiovascular disease data was selected due to this being an example of a long term conditions which emerged as a literature gap in chapter 5. Other long term conditions would also have been of value to study but cardiovascular disease is one of the largest healthcare activity areas. Further justification for selecting this will be explained in chapter 7. The quantitative data identification, capturing and analysis were used to identify Lean wastes within the data. The thesis used data from a variety of sources which again will be explained in details in Chapter 7 however this included the following sources;

1. Open data sources from healthcare providers in Northern Ireland
2. Open data from public bodies responsible for public health initiatives.
3. Open procurement data related to medicines

The exclusion of data was as important as the analysis of the selected data. The data was selected based on the long term condition of cardiovascular diseases and a time periods for the analysis. A key issue in the quantitative data was that there are large volumes of data sets and being able to select and consolidate the data can be difficult. This process was aided by the fact that the author of the thesis has previous experience of working with the health data and implementing large healthcare systems and databases. This need for experience was underlined during a focus group meeting with a cardiologist, healthcare data specialist and health service technology leader. The group could not come to a shared understanding on where they could find the regional data as the clinicians only understands data based on what they see on the screen of a single hospital, not all hospitals, and the healthcare data specialist only understands data based on the field name in a database. The translation between patient facing data, clinical coding of specialist procedures and the technical infrastructure that maps many regional hospitals data to a big data set is a barrier to analysis. The complex data is lacking meta-data documentation that can join the common language to the specific data sets which was addressed during the quantitative data analysis.

Quantitative Data

Challenges

- Data within the healthcare system can be difficult to navigate due to the volume of technical systems, databases and terminology as well as the clinical terminology and coding structures.
- Clinicians, health IT or others will not have sufficient independent knowledge to construct analysis questions on big data sets.
- Ethical consideration of the data prevent explorations of data with unknown outcomes.
- Exclusion of data is as important as inclusion due to the volume of available data.
- Open data cannot be used for most relational queries.

Figure 6.4 – Quantitative Data Challenges in Healthcare

The open data utilised in the research came from various healthcare providers which are listed below. It should be noted that within Northern Ireland, Health and Social Care (HSC) is provided by integrated health and social care trusts. This is a somewhat unique position within the UK as Scotland, Wales and England will manage their care provision frequently separate from the health trust. The implications for the thesis are that data providers are unique to Northern Ireland and to duplicate the research in other localities would require some amendment to the approach from other localities, such as Scotland, may require some additional insight to understand the local HSC structures. An additional context point is that each of the HSC trusts will have a number of hospitals within their responsibility and the Business Services Organisation is a shared service provider across the whole of Northern Ireland for healthcare. Although the GP’s are independent contractors they report their data to regional centres for commissioning and payment purposes. This is largely in line with the QOF data used across the rest of the UK with minor local variations. This data comes from multiple internal healthcare providers including;

- The Department of Health and Social Services in Northern Ireland
- Belfast Health and Social Care Trust
- Northern Health and Social Care Trust
- Southern Health and Social Care Trust
- South Eastern Health and Social Care Trust
- Business Services Organisation
- GP providers

These are all public healthcare organisations who gather the information for commissioning, performance and payment related purposes. There are limits on how much can be derived from the open data as the data is not unique to an individual but to a cohort of patients. There is no ability to join together various outcomes such as the number of patients who have an operation followed by readmitting to hospital. In this case one can see the volume of patients who have the operation and separately one can see patients admitted to hospital on a date after the operation but there is no ability to join these activities together for analysis purposes.

6.4.2 Qualitative Data Sources

During the research preparation and early explorations of the open data it became very clear that although there was a wealth of quantitative data available there was a significant risk to the thesis in not understanding the context; historically, in current practice and in modelling for future Lean models. The quantitative data could provide trends, changes and identify outliers but it was unclear about the reason behind change and the significance of some of the data. For example a spike in costs for a medicine in quantitative data may lead to a false assumption that it may be very bad yet the context may reveal that this reflects cost saving elsewhere in the system. For this reason, qualitative data was deemed to be necessary to bring a richer more complete picture.

Clinicians and other healthcare professionals were used to develop an understanding of the data utilising qualitative approaches. The pragmatism research philosophy supports mixed method research (Jogulu and Pansiri, 2011) with the use of qualitative information to seek the opinion of individuals within the system following quantitative analysis. The opinions were used to clarify information, seek explanation of trends and data that were discovered and seek opinion on research theory emerging. This qualitative approach brought consolidated information, insight and evidence together into interim theory building. In the qualitative data expert opinions derived from interviews were used as suggested by Yin (2011). The expert opinion included;

- Cardiologists
- Heads of Medicines and Pharmacy
- Health Technology Company Leaders
- Heads of Healthcare Service Improvement
- EHealth Directors
- HSC R&D Leaders

The approaches used to gather qualitative data included focus groups, expert opinion meetings and presenting models to various stakeholders at discussion workshops. Due to the nature of the people involved and roles of the participants, many of the discussions were sensitive and it was not appropriate to record conversations. The topic areas that were being discussed were potentially of relevance to major procurements, legal proceedings, media and political parties. For example one of the workshops (WISH Conference, Qatar 2016) was attended with a permanent secretary whose is currently involved in a public enquiry which brought down the Northern Ireland Government in the weeks after the workshop. As the purpose of the thesis and the qualitative data capturing was to seek opinion and engage in discussion, notes from the discussions were taken and written up immediately after each event which served the purpose of the qualitative data and avoided any fear of specific statements being made that could be subject to public scrutiny beyond their purpose.

Focus Groups were used at various stages to input to the thesis as shown in Figure 6.3. Quantitative data was presented to provide a structure data set reflect Lean thinking around wastes and opportunities to improve. Opinions and challenge was sought from the participants to guide the research models emerging. The thesis author led a number of these throughout the time period of the research to guide the outcomes. These included;

- End of Life System Thinking event in Manchester.
- Northern HSC Trust Innovation Group
- NI AMR Network
- NI Cardiology Network

The method of collection of qualitative information was informed by an outline process to maximise the contribution to the thesis. Firstly there was a need to identify the relevant decisions makers based on the Lean value stream map along the care pathway. In some cases this was relatively straightforward as their role was focused on cardiovascular patients. In other cases there was a need to understand that their role may cover a number of areas and cardiovascular patients may only be one part of this. Secondly, where possible the interviews and focus groups were based on emerging data to explore opinions and insights related to the quantitative data. This was to ensure there was a focus and the interviews were in the context of the quantitative data and not distracted by subjective opinions or a current priority. The next step was document and review notes from the discussions which were then codified to identify the information of relevance to the data and the stage of the patient value stream. On occasion information may be discarded as not being related to the cardiovascular scope or not being relevant to the data or value creation for the patient. Following a number of the discussions some topic emerged that required a follow up e-mail or conversation to clarify something stated or where there has been a conflict of opinion. The notes were then used with the chapter 7 research and mapped against the relevant analysis. The notes are available in appendix 2-6.

Examples of where expert opinion brought a richer view of the quantitative data via interviews and focus groups included Cardiologists and Medicines experts due to the specialist knowledge required to understand specific emerging trends in the quantitative data. For example large changes in the reported figures had an explanation around commissioning changes that were not evident from the data and were not publically recorded but understood by experts.

Healthcare technology improvement initiatives were used to provide insight on technology trends and the impact of the emerging research model. The initiatives had their own purpose but the research utilised insights from these research to influence the agenda and explore its utility with various experts. From these insights initiatives that were already underway and barriers that might be encountered where discovered. The changes that were underway are a particularly interesting area as this is often missed because it is not fully documented. Specific information on the qualitative meetings and summary conclusions are available in Appendix 2-6 showing details of the numbers and types of interviews, focus groups and workshops.

Table 6.3 - Sample of other data supporting the thesis – Further details in Appendix 1 and 6

Data was also obtained from the Conferences and Exhibitions:	
Name: Magazine interview via a round discussion with health leaders in the NI Life & Health Sciences Sector. **Participants:**	December 2017 – Published in Agenda NI Magazine in January 2018
Name: Industrial Strategy Challenge Fund Workshops on the Future of Industry **Participants:** Selected life and health science leaders from academia, business and government.	Three sessions throughout 2017 in Belfast and Westminster (*Linked to Prime Minister Teresa May Strategy*)
Name: Innovate UK – LPWAN IOT Healthcare Focus for Northern Ireland **Participants:** NI Councils and Technology Companies	January 2018
Name: NI Life and Health Science Action Planning for Northern Ireland **Participants:** Chaired by NI Permanent Secretary of Health and Permanent Secretary of Enterprise with support from Chief Medical officer and panel of experts from Industry and Academia (PVC & VC nomination).	Sessions in 2016 and 2017.
Name: Industrial Strategy Challenge Fund Workshops – Healthy Ageing workshop – Leading to Government Funding Decisions **Participants:** Selected health and technology leaders across UK. Invitation only from head of Innovate UK.	June 2017
Name: Health Innovation award 2017 **Participants:** Entry to competition with Professor Jim McLaughlin and Dr David Steele. Reviewed in Interview with head of E-health from NI and Ireland. Winning entry for most Innovate solution. Pitch was based on Lean Healthcare approach from thesis.	Feb 2017

6.4.3 Other Data Utilised

Other information utilised included the analysis of grey literature, academic literature and technology horizon scanning. The grey literature and academic literature included working instructions, clinical guidance notes, publications on cardiology and health strategic documents with a focus on cardiovascular disease. Technology horizon scanning was also utilised to collect data through the use of strategic documents, health conferences and exhibitions. These provided information on emerging technologies and were used to identify novel technology that has not been adopted yet but may lead to future patient value. Section 7.7 explores this as a method of identifying trends and developments. A full list of conferences and workshops attended are available in Appendix 6 and workshops of note are highlighted below to show a breadth of input to the thesis from N.Ireland, England USA and Qatar. This is a necessary method of collating data on emerging healthcare technology as the time gap from new technology to literature publication can be extensive due to the rate of change of technology and the length of time for technology to be adopted in healthcare.

In figure 6.2 one can see that the data collected in these horizon scanning and focused literature searches was used alongside the quantitative data to shape the research framework which were explored and tested in the qualitative analysis. Examples of some the horizon scanning workshops reviewed are included in table 6.4 and this is explored further in chapter 7.

Table 6.4 - Sample of Health Technology Conference and Exhibitions - Further details in Appendix 6

Health Conferences and Exhibitions	
Name: Ulster University Health sandpits for mental health and public health **Participants:** Wide interdisciplinary academic group of healthcare leaders in Ulster University	February 2017
Name: EHI Live Birmingham (Largest health technology conference in UK) **Participants:** Healthcare technology companies.	November 2016
Name: E-Health Ireland and Northern Ireland **Participants:** Healthcare technology companies, health leaders and academia.	December, 2016
Name: World Innovation Summit for Health: Doha, Qatar. **Participants:** Invitation only conference. Attended with the permanent secretary of enterprise. Meetings with companies, heads of pharma and medical charities.	December 2016
Name: Longitude Prize workshop in London **Participants:** Longitude Prize participants.	September 2017

6.5 Data collection and analysis methods

The data has been primarily collated and analysed over the period from late 2015 through to late 2017. Earlier data set building of quantitative data was completed to understand the possible data and to develop an understanding of the information available. Similarly explorations of qualitative engagements were completed with focus groups to explore how healthcare providers engaged with Lean, technology and improvement in a healthcare setting but these were later discounted as being out of the scope of the thesis. Figure 6.5 provides and overview of the quantitative and qualitative data gathering and analysis.

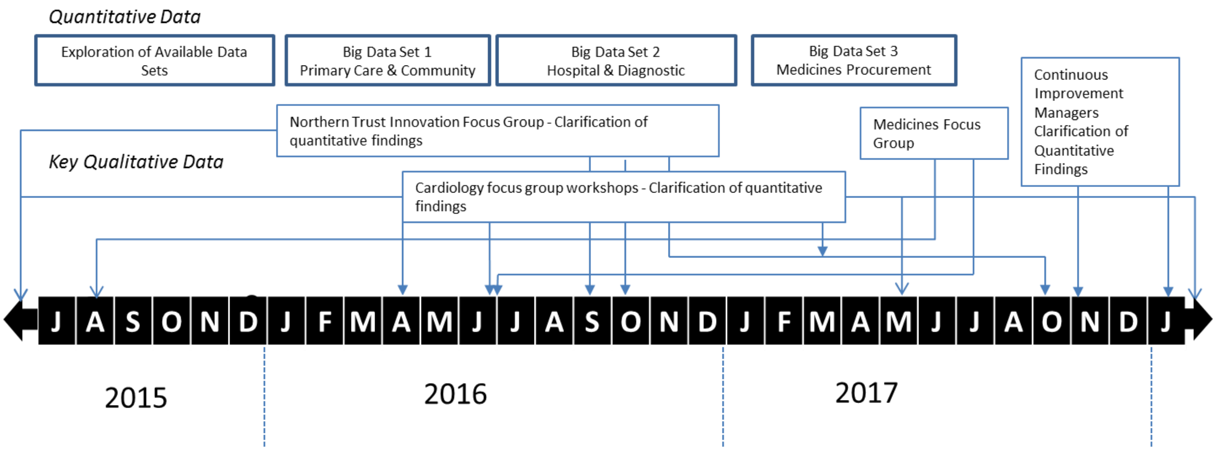


Figure 6.5 – Data Collection Timeline

6.5.1 Quantitative Data

What has been collected for the research is a longitudinal database focusing on a 5 year period from 2011- 2015 inclusive. This has been collected from open source information as mentioned previously in this chapter. The development of the big data set during the thesis required a significant amount of work in identifying and isolating the data. The isolation of the data was due to the large volumes of data that were not relevant to the scope of the thesis such as general surgery or procedure codes that were for other diseases. The data also had to be consolidated across the 5 years to develop a common big data set to compare across the years. Again this required significant amounts of work as the data is not published in this format but published in yearly or quarterly increments. The data also required some cleansing and formatting as groupings or category may have been modified during the time period. Some of the measures may also have been consolidated or removed as a measurement. An assessment of the impact on the thesis of each of these factors has been discussed in chapter 7 at the relevant data section. An example was the removal of obesity measures. The specifics of the data sets are discussed in more detail in chapter 7 and the use of the quantitative data was aligned in the thesis with qualitative data where expert focus groups and individuals were used to make sense of the inductive findings.

6.5.2 Qualitative Data

Figure 6.2 shows how the quantitative data was used to build up data that was then reviewed by focus groups and was a key point of discussion with various experts. The NI Cardiology Network has provided a common grouping to review emerging data and technology. Over the period of the thesis the author has met with the grouping headed by a leading cardiologist of the Ulster hospital on 5 occasions. With the focus of the thesis research being on cardiology this was a very relevant group to work with. He has linked the thesis author with various cardiology related staff at various stages. This was to present and share insights emerging from the analysis and discuss potential options for future health technology within their service to improve quality or address wastes in the system. Further details on this group are available in Appendix 3.

A second group with the Northern HSC trust was started with Una Cunning who was the Director or Elderly care. The remit of the group was to explore waste in the system and the potential for healthcare technology based on emerging data exploration as an evidence trail for improvement. Una retired during the thesis and Gill Smith took on the role of considering innovation and change in the trust and has acted as a link for research. The reason more than one group was identified was due to the nature of the cardiologists focusing on hospital care and the Northern group having more of a community focus. Their separate interests were needed to cover the scope of the patient journey. Further details on this group is available in Appendix 2.

A medicines focus group utilised the expertise of a leading doctor from a medicines optimisation centre, the assistant Chief Pharmacist from the department of health and other staff they would invite to meetings dependent on the availability and interest. This group focused more on medicines data and innovation with the sharing of insights and potential challenges to the emerging data. Again the expertise level they brought was not present in the other two groups therefore the consolidation of the three groups was needed for the thesis scope. Further details on this group are available in Appendix 4.

An improvement manager's focus group was made available to the thesis author through the support of the research supervisors. The group of continuous improvement managers had been engaged with the Ulster University for improvement training and the thesis outline was presented to this group for challenge, comment and criticism. This was then followed up with a workshop with leads from the South Eastern HSC trust. Further details on this group are available in Appendix 5.

Research Ethics

6.6 Research validity

Burns (2003, p. 160) stresses that "validity is an essential criterion for evaluating the quality and acceptability of research therefore mixed methods have been used to allow "qualitative methods to explain quantitative results" (Jogulu and Pansiri, 2011, p. 690) therefore improving the quality of the research data collection methods and the conclusions the research reaches.

The data collection is based on data which is openly published as government data. The level of professionalism in creating the data and level of scrutiny that the data is under brings reassurance that the quantitative data is valid. The use of data in the health service is dependent on the quality of data and this is known to be linked to the age of the data, which entered the data and the level of buy in for the quality. The collection of quality data was initially low on the priorities within healthcare providers as it was largely seen as an accounting exercise and delegated to junior clinical or admin staff who would complete various forms that had limited impact on operational activity. As the use of data in healthcare has moved from accounting for activities to clinical utility the data quality has been required to improve as clinical decisions are based on the data and the related governance has improved. Clinical coding standards, such as ICD 9 and 10 coding, have changed over time in terms of the definition of the coding, quality of the coding and use of coding. In expert discussions during the thesis it was suggested that the hospital data was robust due to the number of years it has been operational and tested. Public health and community based data was under less scrutiny and open to more risk of errors and lack of robust adherence to standards. The qualitative data reliability depends on its credibility as suggested by Yin (2011) and Burns (2003). The interviews were all conducted by recognised experts in the field of healthcare and the area of cardiology in particular. Similarly the focus groups participants all were recognised experts and leaders in their respective fields thus adding validity to the research findings. Furthermore, as suggested by Saunders and Tosey (2013) the longitudinal nature of the data added validity by overcoming point in time observation limitations. The mixed method approach involving different data sources also added to validity through strengthened triangulation of the data as suggested by Jogulu and Pansiri (2011).

6.7 Reliability

Reliability deals with the dependability of the information and the ability to replicate any piece of research (Kolbe et al., 1991). The quantitative data is reliable as the ability to recreate the information from the open data is available to any potential user due to it being open source. Moreover the method of analysing this data has been made explicit through the research with assumptions and rules stated, Observation or conclusions reached from the qualitative data have been open to scrutiny within the thesis. With qualitative data, achieving the identical results is difficult because the data is in narrative form and subjective. Lincoln and Guba (1985, p. 288) point out that instead of obtaining the same results, the focus is on the dependability and consistency of the data. The purpose is to agree that given the same data collection processes the findings are consistent and dependable. Throughout the qualitative data gathering this was achieved by using expert opinions over a longitudinal period. Moreover, these qualitative sources were iteratively compared and contrasted in establishing findings. Overall, the mixed methods also add some reliability by ensuring the dependability of the findings rather than relying on single sources or methods (Lincoln and Guba, 1985).

6.8 Generalisability

Generalisability of the quantitative research can be made for the concepts and principles that have been drawn out however the thesis data is focused on cardiovascular disease data for Northern Ireland within a specific timeframe from 2011 – 2015. For this reason, although the patterns are likely to be transferable to other conditions, locations and time periods this will need to be tested. Generalisability of the qualitative research findings is usually not an expected attribute; however, analytical generalisation can be applied where the extent to which the current findings can be generalised to another using the theoretical framework developed in the research as a basis for further study (Brinkmann and Kvale, 2015). This analytical generalisation in the thesis draws upon both the quantitative and qualitative data synthesis in the theory building process (Zimmer, 2006) which is discussed in chapter 9.

6.9 Research Limitations

In relation to the quantitative big data sets the author ultimately had to make a choice to focus on cardiology. This omitted other big data sets relating to other healthcare conditions, such as respiratory diseases, where there is substantial opportunity to explore the research aim further. These opportunities are referred to in the opportunities for further research section in

Chapter 10. The qualitative data had limitations consistent with all qualitative research due to the number of sources of data, however concept building data saturation (Yin, 2011) which helped addresses this limitation. Another limitation was that due to the sensitivity of the expert interviews and focus groups the conversations could not be recorded adding a limitation on data accuracy. However the longitudinal nature of the research coupled with note taking during and immediately after the qualitative events mitigated this risk.

6.10 Summarising the Methodology and Revising the Aims and Objectives

The aims and objectives were outlined in section 1.4 and as objectives 1 & 2 have now been completed, a fuller explanation of the aims and objectives has been created and can now develop with the research. This utilises the identified gaps in the literature and learning from the literature review on Lean and Healthcare technology and the potential wastes. The research in chapter 7 focuses on gathering empirical evidence which is focused on understanding cardiovascular patients as an example of a long term condition. The research data collected will use quantitative and qualitative data approaches to identify new wastes from data sources related to a defined patient group within cardiovascular disease. The Lean wastes which have been identified within the literature in chapter 3 will be a target area for the research as these can be mapped on to the cardiovascular disease pathways.

Chapter 7 – Cardiovascular Disease Analysis and Results

7.1 Introduction

Chapter 5 identified a gap for academic research to explore where Lean healthcare reform and emerging data related technologies could reveal novel insights if focused on healthcare delivery for long term conditions. To develop the thesis further, this section will focus on cardiovascular disease related conditions as an example of a long term condition. The section will examine the various silos of healthcare delivery to identify the current Lean wastes and non-value add activities before bringing the overall healthcare delivery value stream together. The same approach could be applied to other long term health conditions and the lessons learned although benefiting from a focus on cardiovascular disease patients will be developed in a way to allow them to be transferable to other conditions. As a long term condition, cardiovascular disease impacts high volumes of patient activity requiring management in the hospital, in the community, with medication and impacting personal dietary decisions. It is one of the dominant non-communicable diseases on the global disease list. The World Health Organisation (2017) reported in May 2017 that;

- Cardiovascular disease is the number one cause of death globally
- 17.7m people died from cardiovascular disease in 2015
- 31% of deaths worldwide were cardiovascular disease related in 2015
- Over 75% of cardiovascular diseases occur in low and middle income countries
- It is possible to prevent the majority of cardiovascular diseases

The World Health Organisation (2017) statistics also note that much of the disease can be prevented by addressing risk factors. The risk factors include diet, exercise, alcohol and tobacco (NICE, 2017). It also highlights that people with known risk factors should be the subject of appropriate treatment and management of the risk (Riebe et al., 2015).

Cardiovascular disease was selected for the thesis due to the scales of the disease, the impact on patients, and the evidence of the disease being preventable.

To develop the thesis further and address objective 3 and objective 4, the remainder of this chapter will analyse cardiovascular disease as outlined in figure 7.1.1. Objective 3 aims to "investigate use of emerging technology to address improvement areas identified" and objective 4 aims to "explore the development of a theoretical framework for Lean healthcare technology models which utilises the learning and approaches of Lean and opportunities presented by technology". Chapter 7 will identify the areas for improvement and existing technology with the theoretical models being discussed and developed in chapter 8 & 9.

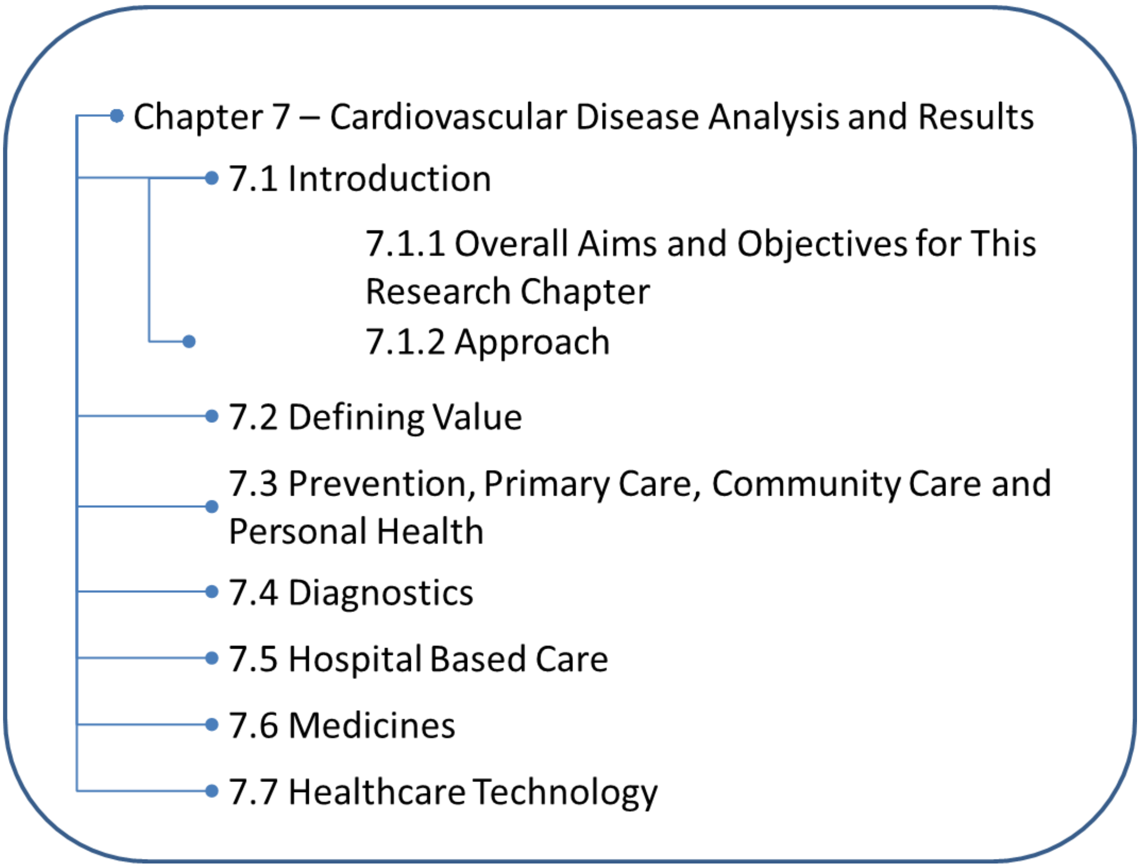


Figure 7.1.1 – Chapter 7 Overview

7.1.1 Overall Aims and Objectives for This Research Chapter

Taking into account the research methodology laid out in chapter 6, the aim of this chapter of the thesis is to explore cardiovascular disease as an example of a long term condition which requires an integrated healthcare pathway. The chapter will address the aim of the thesis by;

> Exploring the role of Lean thinking in cardiovascular disease activities to identify opportunities for improved healthcare technology.

This chapter will study the delivery of healthcare and management of patients with cardiovascular disease as an example of a long term condition to allow research question 1 to be addressed. The thesis will also consider how the application of new technology can identify waste or non-value within the system to address research question 2. Thirdly the chapter will assess which activities bring value to cardiovascular disease patients and how data can assist this to address research question 3. The thesis will analyse activities related to the delivery of cardiovascular disease healthcare with the aim of exploring a new model to assist in considering Lean healthcare waste and technology adoption. The analysis will include a number of types of technology used for care delivery in cardiovascular disease today such as heart monitors, bio markers, pacemakers and blood pressure monitors. The research will utilise open data associated to cardiovascular disease healthcare provision to create a longitudinal data set to assist with analysis of patient flows. From this an assessment of technology adoption opportunities will be identified in line with the research questions. This approach will allow the thesis to answer the research questions of identifying how Lean can be adapted for long term conditions, can health technology assist in identifying and addressing Lean non-value activities and can healthcare technology assist in redefining patient value.

7.1.2 Approach

The research utilises the core Lean principles (Womack and Jones, 2010) as a template to consider how cardiovascular disease treatment is delivered today. These core Lean principles are reflected across the majority of Lean literature today including Miller (2015). The core Lean principles are addressed in this chapter in the following way;

- **Identify Value** – Value for the cardiovascular disease patient is analysed as an example of a long term condition in section 7.2.
- **Identify Value Stream** – Section 7.3, 7.4, 7.5 and 7.6 reflect the key value stream activities for cardiovascular disease.
- **Make it Flow -** The Lean failure and non-value add activities have been identified in chapter 3 based on available Lean healthcare literature. The outputs from section 3 will be used as a template to be populated with the specific evidence of cardiovascular disease wastes and non-value add activities found through the use of available articles, grey materials and open data
- **Pull to customer** – Analysis of the Northern Ireland cardiovascular disease open data and statistics to understand the demand for various activities will be analysed through a longitudinal data set for over 5 years.
- **Strive for Perfection –** In each section from 7.3 to 7.7 there will be an exploration to understand emerging models of care and also the future use of technology. The use of wider insights from health and academic leads through qualitative analysis will also complement existing exploration of data and guidance.

The uses of these approaches are explained through the remainder of this section and will be reflected in each later section in the chapter.

7.1.2.1 Defining Value

Defining value is a first step for all Lean approaches and the analysis will start with considering Lean for the cardiovascular patient. While the intention is that a combination of referrals, diagnostics, tests and procedure are intended to address health and social care needs this section will assess value for the patient from a Lean perspective using qualitative analysis. Section 7.2 will consider value prior to addressing the questions about the specific activities in healthcare. This is an essential starting point to address research question 3 which is focused on health technology being used to redefine patient value. It is also a key part of research question 1 for considering how Lean can be adapted to address long term conditions.

7.1.2.2 Identify the key activities currently performed

Following a review of qualitative analysis, quantitative data analysis, existing literature, exploration of the subject areas and exploration of Lean in health care the following areas were identified as the main activities or topic categories which have a direct impact on cardiovascular disease patients.

- Prevention, Primary Care, Community Care and Personal Health (7.3)
- Diagnostics (7.4)
- Hospital Based Care (7.5)
- Medicines (7.6)
- Technology (7.7)

Each of the categories provides insight on healthcare delivery or Lean non-value add and jointly they provide a patient pathway view of healthcare value. These areas emerge from reviews of literature and cardiovascular disease best practice guides. The reason for their inclusion and explanation of their purpose will be explained in the introduction to each of the sections.

7.1.2.3 Analysis of Current Interventions Globally in Research Articles and Grey Materials

In each of the sections 7.2 – 7.7 there will be an analysis of the current interventions which are brought together from qualitative analysis, academic papers and grey documented materials. This will assist in addressing research question 2 about identifying the Lean non-value add activities. Healthcare has a significant amount of grey materials and guidance which is uncommon to other industries and this thesis makes use of the availability of such material to identify potential non-value add activities. This will complement quantitative data collection as there are activities that are not measured and don't have significant quantitative data associated to them.

The primary focus is on cardiovascular disease from the Northern Ireland region therefore the guidance focus will be on NICE guidance which is the recognised standard for the HSC in Northern Ireland. The use of clinical guidance, instructions and procedural best practice instructions provide an insight into the key activities and wastes within a system. NICE guidance documentation will be used as a method of understanding non adherence to best practice. The NICE guidance documents in table 7.1.1 have been identified as relevant to the cardiovascular disease focus area.

Table 7.1.1 – Standard Operating Procedures from the National Institute of Clinical Excellence (NICE) - "Cardiovascular conditions: general and other"

Standard Operating Procedure Title	Reference
Cardiovascular disease prevention	PH25 (NICE 2010)
Cardiovascular disease: identifying and supporting people most at risk of dying early	PH15 (NICE 2008)
Cardiovascular disease: risk assessment and reduction, including lipid modification	CG181 (NICE 2016)
Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures	CG64 (NICE 2016)

The details in the NICE guidance in table 7.1.1 provides some insights into the clinical non-value activities, however in researching the topic it becomes clear that there is large volumes of material covering the mapping of services, diagnostic guidance, innovation briefings, quality standards, appraisal guidance, technologies guidance as well as "in development" documents. This was all within one category of cardiovascular disease called "Cardiovascular conditions: general and other". There was similar information available for 13 other conditions such as acute coronary syndromes and aortic aneurysms.

As the purpose of the thesis is not clinical the thesis has focused on "cardiovascular conditions: general and other" (NICE 2017) as an example of the types of guidance at the centre of cardiovascular disease rather than spread into specific clinical specialty. From this, sufficient contribution should be made to the research questions which would have application to the other areas. Also as this analysis is being "triangulated" with other qualitative and quantitative data there is an opportunity to identify any gaps from this approach through the data (Jogulu and Pansiri, 2011).

7.1.2.4 Analysis of Current Measures and Data within the System

This will focus on the quantitative data available and specifically on cardiovascular quantitative data. A longitudinal data set for over 5 years has been used for analysis. The data sets are based in the section topic such as medicines or diagnostics linked to cardiovascular disease. Analysis of relevant data for the topic and discussing the strengths and weaknesses of the data within the Lean context of identifying non-value add and waste will assist in the research questions. Open data sets are available to cover areas such as waits, procedures and medicines. This provides a rich source of information to compare, contrast and identify potential Lean non-value add activities and variances in practice and outcomes.

The majority of the data used in the quantitative analysis in the area of cardiovascular disease is sourced from a data silo such as the GP, hospital or medicines provider. The thesis has provided a new contribution by developing analysis across these data silos. Figure 7.1.2 provides an overview of the various data sets and providers that the analysis is collected across. This figure is repeated in each of the section with the area being focused on in that section highlighted to assist in navigating the thesis topic.

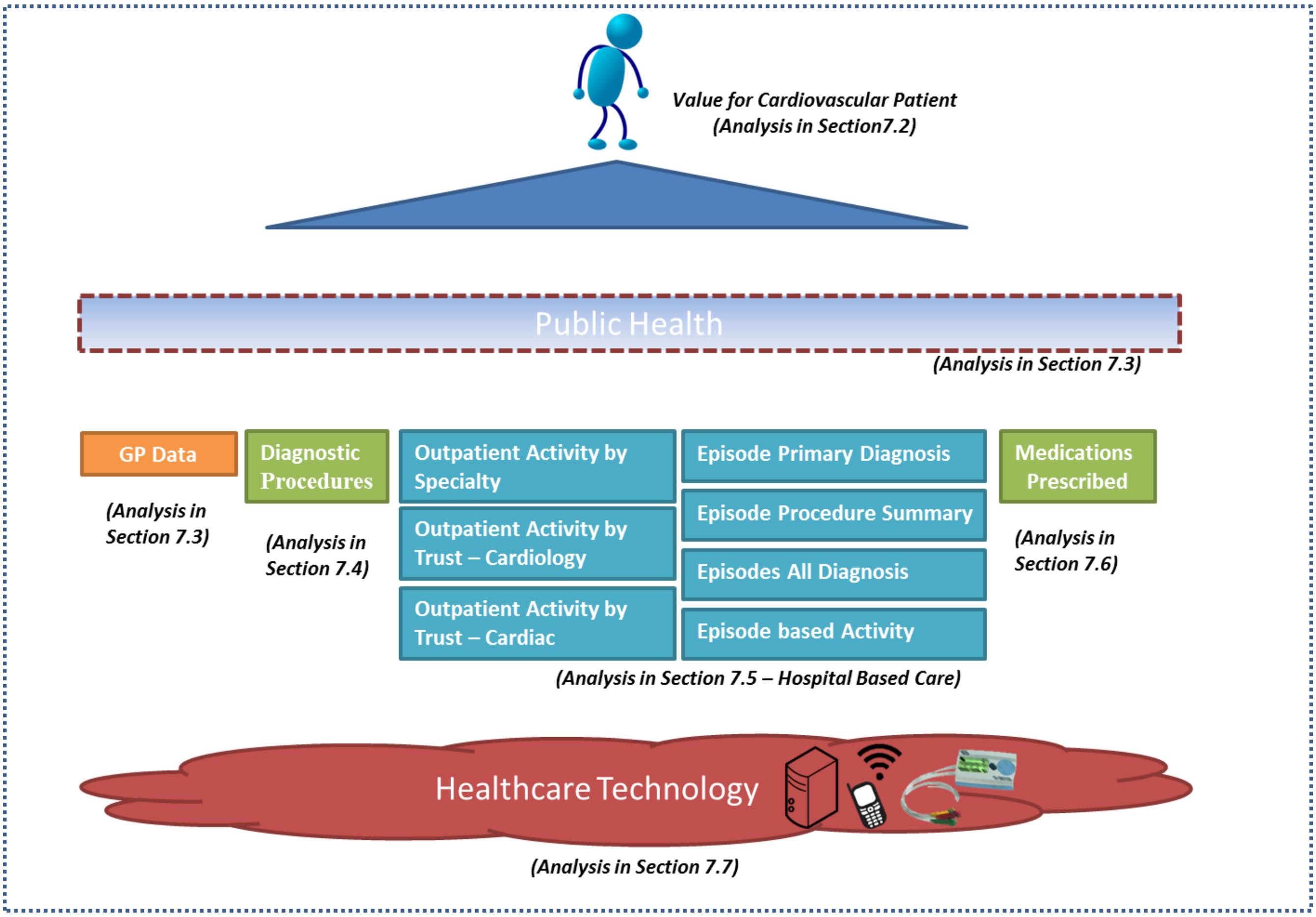


Figure 7.1.2 – Cardiovascular Disease Data Set

This required grouping together of data in common formats and the exclusion of data which is appropriate to other conditions. On occasion data definitions and recording methods have caused some gaps or changes. For example the recording for one year may have been grouped as 1-6 weeks in one year's data and in the following year that group was not available but had been replaced by another 2 groups called 1-3 and 4-6. Comments and methods of dealing with these changes are documented at the relevant section. The below highlights the sources that have been used for data and during the analysis.

Table 7.1.2 – Longitudinal Data Set for Cardiovascular Disease

Data Area	Location	Description	Comment
GP Data	Northern Ireland Region	Quality Outcomes Framework (QOF) Data.	Primarily Collected to quantify payments to GP's *(Department of Health 2017)*
Hospital Data	Northern Ireland Region	Including: Outpatient Activity and Rates by Specialty - Outpatient Activity by Trust – Cardiac - Outpatient Activity by Trust – Cardiology - Episode based Activity - Episode Primary Diagnosis - Episodes All Diagnosis - Episode Procedure Summary	Collected for Performance Management of the 5 NI Health and Social Care Trusts. *(Information and analysis directorate 2017)*
Diagnostic Data	Northern Ireland Region	Diagnostics Data	Collected for Performance Management *(Information and analysis directorate 2017)*
Medication Data	Northern Ireland Region	Prescription Cost Analysis Northern Ireland - Consolidated from Across 2010 - 2014	Collected for Transparency of Government spending. *(Business Services Organisation 2017)*

7.1.2.5 Lean Wastes/ Lean Non Value-Add Activities

The literature review in chapter 3 focused on Lean wastes or non-value add activities in Lean healthcare literature. The approach that has been adopted for the research in this thesis is to use the findings from chapter 3 literature review as a template to apply to cardiovascular disease activities.. The chapter 3 template is provided in Table 7.1.3 for ease of reading. This approach reflects the original manufacturing application of Lean where they utilise the “seven wastes” (Womack and Jones, 2010) as a guide to identifying non-value as these can be common issues across industries. The purpose of the thesis is to discover these wastes in a long term condition and to develop a model of relevance to Lean healthcare technology adoption for long term conditions.

Table 7.1.3 - Chapter 3 Literature Review Output of Lean Healthcare Non-Value Add or Waste

Healthcare Failure Area Identified in Chapter 3	*Description*
Waiting times	*Awaiting treatment to begin*
Delays	*Waiting for activities, results while being treated*
Activity Transaction Speed	*Related to activities within the value stream*
Diagnostic	*Turn-around times*
Medical Complexity	*Increasing strokes risks and amputations*
Additional Healthcare Visits	*Follow up, review or further appointments than necessary*
Co-ordination of Healthcare resources	*Often lack of coordination producing additional activities*
Stress/overload of staff	*Often driven by lack of clarity and inefficient processes*
Repeated Procedures	*Missing test result, records or updates requiring repeated work*
Motion/Transport	*Including staff walking*
Length of Stay	*Average length of stay is a key measure of hospital performance but needs to be balanced with readmission rates*
Cost	*Wasted money and processing additional claims*

	or costs
Quality	*Errors in practice or administration of care*
Emergency Admissions	*Unplanned, avoidable admissions regarded as a failure in the system. For example an escalation in a condition which could have been prevented*
Death	*Unnecessary mortality due to falls, infections, Turn-around times*
Medication errors	*Wrong drug, dosage or administration*
Infections	*Caused by the medical interventions or environment of medical intervention*
Emerging from this research and not covered in Lean Healthcare Literature	*In each of the sections there will be a final row to highlight waste and non-value add activities that have been identified in the analysis which were not included in Lean healthcare literature from Chapter 3. This will assist in addressing research question 1 about how Lean can be adapted for long term conditions.*

7.1.2.6 Use of focus groups and expert opinion cardiologists to complement existing exploration of data and guidance

The approach of the overall thesis as laid out in chapter 6 has been to utilise a mixed method approach therefore in addition to the quantitative data mentioned qualitative data has been sought from leading experts. Expertise has been sought through focus groups, meetings and discussions listed in appendix 2-6 and with the following being example of the types of contributors;

- Cardiologists
- Pharmacy Leaders
- Health Technology Businesses
- NI Life and Health Science Senior Leaders

7.1.2.7 Review of Technology

The approach of the overall thesis has been to utilise Lean as a method of identifying opportunities for technology to address the non-value add for patients. The thesis explores technology match to cardiovascular disease through the following three separate sources;

- **National Strategic Healthcare Programmes, Implementations and Literature** – This reflect the demand side where healthcare providers either have the technology or have an intent to adopt it.
- **Emerging Supplier Commercial Offerings** – The technology providers are often developing new offerings that may address a need in healthcare. Analysis is provided in section 7.7.
- **UK Government Innovation Funding** - The thesis has made use of published data from Innovate UK funds awarded to emerging innovations in healthcare.

This approach for healthcare technology will complement the research. When combined with the quantitative data and qualitative data this will provides a more complete picture to assist with research questions 2 & 3 which will utilise technology for the Lean wastes (question 2) and for the redefining value (question3).

7.1.2.8 Summary of Research Approach

To summarise the approach of the remainder of this chapter, the thesis research questions will be addressed by analysing the following key topics which are relevant to cardiovascular disease;

- Defining Value in section 7.2
- Prevention, Primary Care, Community Care and Personal Health in section 7.3
- Diagnostics in 7.4
- Hospital Based Care in 7.5
- Medicines in 7.6

- Technology in 7.7

Within each topic, the analysis will include a common approach in each section of the addressing the following areas;

- A brief introduction to the topic area
- Analysis of current interventions globally in research articles and grey materials
- Analysis of current measures and data within the system
- Reflection on what is not measured
- Lean wastes/ Lean non value-add activities

By completing the analysis, this will lead to a discussion aligned to the thesis aims, objectives and research questions. A short discussion will be available in each section which will then be consolidated to provide a wider discussion bringing together findings from academic literature in chapters 2- 6 with the research analysis findings of chapter 7.

7.2 Defining Value

Central to Lean is the importance of starting by defining value (Womack and Jones, 2010). To begin analysing cardiovascular disease from a Lean perspective one must prioritise consideration of value and the purpose of the system prior to progressing to the processes and activities. This section will explore the understanding of what "value" is for cardiovascular disease prior to defining the activities which are required to deliver this value.

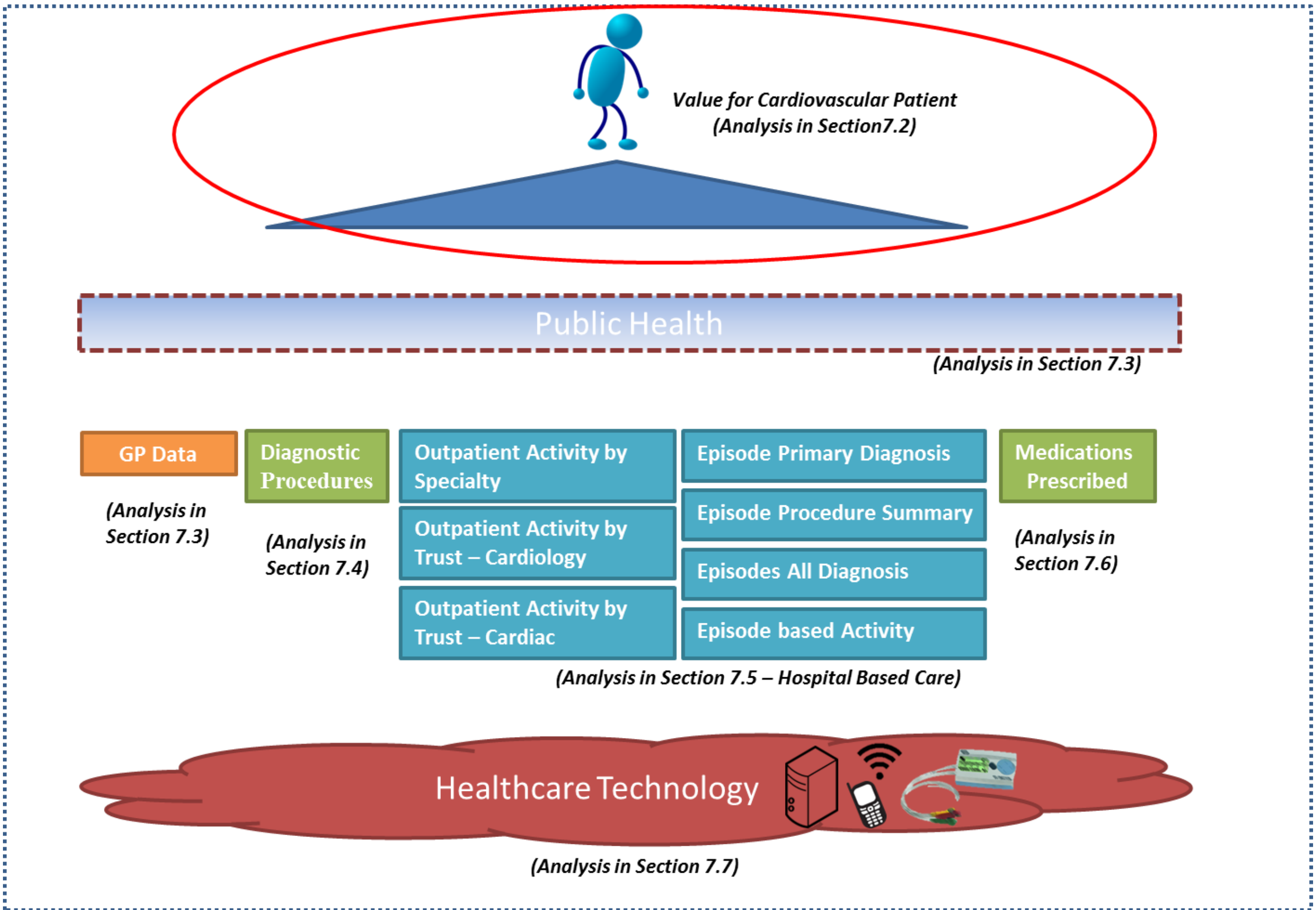


Figure 7.2.1 – Cardiovascular Disease Data Set – Focus on Value

7.2.1.1 Definition of Value

The definition of value will be explored throughout this section but setting some context to what value is, Porter (2010, pg. 2477) highlights that value has an "overarching goal of healthcare" and is linked to health outcomes rather than dollars spent or activities performed. While this may seem obvious, the reality is that hospital and care providers are measured based on activity and volumes and not patient outcomes. The value that will be discussed in this chapter will therefore refer to patient value and measurements around the patient rather than the system.

7.2.1.2 The Role of Value

Arguably the role of value has been limited in care provision with providers focusing on care activities. The result is disjointed services than can conflict, create gaps and lead to duplication. This is however changing as value is a key focus of emerging reform and Porter (2016) notes that USA public health organisations Medicare and Medicaid are moving towards a value based reimbursement.

7.2.1.3 The Future Development of Value

The research question of how Lean can be adapted for long term conditions has to consider value for patients. The current healthcare system is designed on sequential activities followed by review and discharge. There is limited consideration of how to manage a long term condition patient who may have multiple care engagements over a number of years dealing with many different care providers (Patton et al., 2015). Similar to the sequential way the healthcare system has been designed around a linear process, Lean has the flow concept and sequential activities as the main basis of its approach. The question to be explored therefore is about what would need to be adapted for Lean to work with long term conditions.

7.2.1.4 Value in this Thesis

The remainder of section 7.2 will analyse what is meant by value for long term condition patients and specifically cardiovascular disease patients. Value, while not a key activity in itself defines the activities that will be completed. Understanding value will have major impacts on activities, wastes, measures, staff and patients. The remainder of this section will consider;

- Analysis of current diagnostic interventions in academic and grey papers
- Analysis of current measures and quantitative data within the NI healthcare system
- Consider what is not measured
- Map the activities against the Lean non-value add activities identified in academic literature chapters 2-4.

From this analysis one can then contribute to answering the three research questions of how Lean can be adapted for long term conditions (research question 1) and contribute to identifying methods for healthcare technology to address Lean non-value add activities (research question 2). The analysis will help identify where value is not being delivered. This will assist in building the case for technology addressing a redefined value in research question 3.

7.2.2 Analysis of Current Interventions Globally in Research Articles and Grey Materials

Current healthcare delivery is based on a series of activities, often described as episodes of care, such as a medical intervention. The activities will be joined together as a care pathway which can reflect the Lean value stream. Where activities are beyond the responsibility of an organisation then a referral is made to another provider, such as a social worker. The complex nature of care provision may mean that the care pathway does not address holistic patient needs such as respiratory problems or depression issues (Mazzocato et al., 2014). The result is that complete patient value may be inadequately addressed or waste may have been created through the conflicts of treatment, handovers and lack of flow. The combination of activities is dictated by the commissioner of the service rather than the patient. This largely reflects guidance from clinical experts however local decisions can result in variance across the UK on the services delivered.

While the term value creation is not frequently found in the care provision the pursuit of "quality" is a dominant term (White et al., 2017). Waiting list measures, number of procedures, length of hospital stays, infection occurrences and measures associated to life after a procedure are often measured. Service improvements, quality, training and commissioning models are built around these operational and clinical measures. Process measures linked to quality have sought to find ways to compare and contrast best practice which has led to care plans, care pathways and guidance emerging. Examples of these are NICE guidance and the productive ward series of improvements (White et al., 2017). These standardise best practice processes when applied begin to reduce errors, control infection and manage risks. The various measures used in healthcare are not without criticism with the media and politicians advocating or criticising various measures. Evidence of "gaming" the measure has also been seen as senior health leaders have sought to avoid the repercussions of perceived poor performance. The Guardian on the 17 Dec, 2014 reported on the Care Quality Commissions investigations into two separate inquiries in Colchester Hospital around the manipulation of cancer waiting times and accusations of staff being bullied to change data to meet targets. In this incident there was no evidence of system wide manipulation however there was recognition of sub-optimal care being provided and staff under pressure to meet targets. This enquiry is representative of similar investigations in other hospital and raises questions about the measures and if they are incentivising unintended consequences that don't relate to patient value.

The concept of value based models have been considered with Chris Ham, Chief Executive of the Kings Fund, highlighting that "in a cash constrained public health service with ambitious targets being required in the "five years forward" strategy focusing on "..better value is the most promising way of realising the eye-watering productivity improvements..."

(Ham, 2016, pg. 1). Similarly in the USA, the 2015 report to congress highlighted that fee for service programmes lead to overprovision and perverse provider incentives (Congress, 2015). These shifts towards value based models, away from activity models, is of interest to this thesis as it recognises that value is not the current focus of healthcare delivery therefore moving to alternative commissioning models linked to health outcomes has significant merit (Reuben and Tinetti, 2012). The challenge for Lean in cardiovascular disease is that one must understand;

- Who is the customer?
- What do they value?
- Barriers to delivering value.

The rest of this section explores further the understanding of value from the patient's perspective. The implications are that Lean wastes will be evident as value has not been clearly defined from the customer's perspective.

7.2.2.1 Who is the Customer?

The Lean "customer" is complex in cardiovascular disease as there are various budget holders, commissioners, trusts, patients and family members as users and contributors acting in a consuming way. The compliance of the patient to health and medical guidance will mean that patients are not only a consumer but also a contributor to better health outcomes (World Health Organization, 2017). Lean seeks to define value for the customer (Womack et Al., 1991) but in the case of healthcare, defining who the customer is can be challenging. Brill (2013) focusing on American healthcare, highlights that the insurer, employer who chooses the insurance and the patient who chooses the insurer all have an influence on the care provided and the costs of care. Multiple stakeholders result in conflicting interest, multiple ownership, complex decision making and changing priorities which make it difficult or impossible to create unified goals in a manner not evident in other industries (Eldabi, 2009). Due to the issues outlined, this thesis will focus on value creation for the individual patient. The patient will be the customer in Lean terminology and all waste will be measured from this viewpoint. The consequence of focusing on other stakeholders is to drive non-value creation which may reduce patient outcomes and increase costs. This is illustrated within a Time article that highlights US healthcare organisations incentives to provide surplus tests, over-treat and address system goals where patient value is not the focus (Brill, 2013). In summary, placing the patient as the customer and seeking to deliver value for them is an important approach for Lean in cardiovascular disease.

7.2.2.2 What is Value for the Patient?

A number of studies have been published which explore differences between hospital care and a “hospital at home” provide insight around defining value for the patient ((Patel et al., 2008, Garcia-Soleto et al., 2013 and Mendoza et al 2009). The studies are relevant as moving care away from the hospital has required the authors to consider patient value. Table 7.2.1 highlights the variety of measures of value used that recognises that clinical improvement was only one measure but cost and quality of life were also important comparators.

Table 7.2.1 Cardiovascular Disease Trial Reviews - Measures of Comparison used to Represent Value

Clinical Trial Paper	Number of Patients	Country	Measures Used to Represent Value
Patel et al., 2008	31	Sweden	(1) Was symptomatically stable or improving, (2) had stable falling weight, (3) had no signs of pulmonary rates and (4) had no oedema above the ankle
Mendoza et al., 2009	71	Spain	Avoiding readmissions Absence of symptoms or reduced symptoms Blood measures which indicate decline or improvement such as– pro BNP, Health related Quality of Life Functional status * Health-related quality of life **
Garcia - Soleto et al., , 2013	71	Spain	Functional Status** and Health Related Quality of Life ** & ***Minnesota Living with Heart Failure Questionnaires which focus on quality of life.
*Barthel Index –Short questionnaire which makes an assessment based on 10 items around quality of life. **SF-36 – Structured quality of life questionnaire covering physical, social, emotional and mental health. ***EQ-5D – Rating score based on 5 dimensions of mobility, self-care, daily activities, pain/discomfort and anxiety/depression.			

Garcia-Soleto et al. (2013), reported in the discussions about quality of life as distinct from the physical, bodily function and general health. They recognised that in many cases the baseline for quality of life can be complex as initial "decomposition" or clinical incident will result in lower quality followed by a ramp of improvement to a new baseline. The studies report no significant difference in clinical incidence between the home or hospital care therefore the studies explored further the concept of value connected to quality of life and cost. Value has also been explored further in healthcare simulation work where seven axis of values were identified including; prolonging the absence of illness, minimising pain, maximising periods of health, maximising mobility, maximising independence, contributing to society, reducing isolation and enjoying a quality of life (Kuljis et al., 2007). From these studies one can see that the value for cardiovascular disease patients is complex and falls beyond the direct clinical activities which could be summarised in the categories outlined in the table 7.2.2.

Table 7.2.2 – Analysis of Wider Measures for a Cardiovascular Patient

Measure	**Examples**	Reference
System Outcome Measures	• Discharged Alive • Reduced Readmission • Mortality - Preventing people from dying prematurely	Example: The epidemiology of cardiovascular disease in the UK 2014 (Bhatnagar et al., 2015)
Patient Functionality Measures	• Speed to Re-ablement - *post-hospital return to maximum independence and recovery from episodes of ill health or following injury* • Exercise Tolerance	Cardiac rehabilitation programmes being regarded as best practice but not widespread – (Yohannes et al., 2010)
Process Based	The system wide measures include; • Quantity of patients managed by GP with specific cardiology diseases such as Heart Failure • Waiting list statistics • Appointment details, Episode details, procedure counts.	Department of health official published waiting times for figures such as waiting statistics and activity measures. (Information & analysis directorate, 2017)

	• Uptake of cardiac	
Customer Service	• Patient experience	Public Satisfaction Surveys are completed infrequently by commissioned surveys such as National Centre for Social Research's British Social Attitudes. Commissioned surveys are also completed by various trusts and commissioners and charities to progress a number of agendas from reform through to lobbying for additional funding.
End of Life Planning	End of Life Plan in Place – people at end of life are often not identified and therefore treated incorrectly	Treatment and Care Towards the End of Life – (General Medical Council, 2018)

Table 7.2.2. highlights a maturity in the measures around process but a weakness in all other areas. This is reflected in the qualitative discussion where the cardiologists suggested that they focused on clinical intervention first before considering the patient consideration of end of life. Similarly the lack of quantitative measures around quality of care across the whole care of the patient reflects missing value measures. In these other areas, the measures are often absent of regular data with those that are completed representing a one off measurement, infrequent measurement or inconsistency across regions. This reflects the earlier outputs of the thesis that measures and Lean literature has focused on organisation silos rather than patient value. The term quality appears frequently as a proxy for value which may not be true as a quality measure will look at the how a diagnostic procedure was completed but may not question if the procedure was needed or value to the patient's personal value measures. This is highlighted in the large variance between US providers and

other countries in reference to the number of procedures or diagnostic tests without the resultant improvement in health outcomes (Brill, 2013).

In summary, the existing measures may not correspond with patient value measures for cardiovascular patients. Some of the areas that are measured are not relevant and some of the areas of value are not measured. Although not connected to the cardiology study the following quote reflects the position on understanding value well;

> *"Alan A. didn't care how much time his cancer or heart doctor spent with him or how many tests he got. He cared only that he got better" (Brill, 2013, pg. 36).*

This lead to a position of needing to understand what is preventing value from being delivered in cardiovascular disease.

7.2.2.3 Barriers to Delivering Value

A number of barriers emerge from healthcare studies and grey materials when looking at cardiovascular disease. The organisation of healthcare workers is one area of failure as healthcare with a lack of interdisciplinary work targeted at patient value can produce waste (Reiter et al., 2016). Secondly, patients themselves can be a barrier as the levels of adherence to medication, smoking cessation, weight control, exercise participation, positive mental health and participation in community activities all have an influence on cardiovascular disease therapy and the related outcomes (World Health Organization, 2017). The area of medicines adherence was a significant topic for the medicines focus group (Appendix 4) in the qualitative analysis as they are currently engaged in a number of explorations of technology to address patient adherence issues in medication. Thirdly, a lack of understanding on what is value for a patient can be a barrier as patients may make trade off decisions which are not understood by healthcare providers as part of managing their condition. For example a patient may choose additional pain over the side effects of a toxic drug which reduces their ability to take part in a social event or milestone family event such as a daughter's wedding. NICE cardiac rehabilitation services guidance recognises the patient as being a co-creator in Value and the need to ensure the patients ability to manage their own condition, access support and make personal decisions about care (NICE, 2017). Fourthly treatment can fail to consider the full patient value with some treatments being inappropriate for patients approaching end of life and therefore bringing discomfort. This area emerged in the qualitative analysis with the heart failure nurse (Appendix 3), as patients with heart failure may be moving towards end of life which may require different treatments and approaches to care. Examples include treatments which focus on short term biological measures which may be appropriate on healthy patients but be inappropriate for severe disability, multiple conditions and those with a short life expectancy, prolonging the process of dying and causing unnecessary pain (Reuben 2012). Finally, "bad care" which will harm the patients is a barrier to value. With $4.4BN paid by Medicare in the USA for patients harmed in hospital in 2009 this is evident of "bad care" in todays practice (Brill, 2013).

In summarising, one can see that healthcare staff silos, patients adherence, inappropriate care for those at the end of life and the impact of bad healthcare can all be barriers to healthcare value delivery.

7.2.3 Analysis of Current Data within the System to Build a Lean Value Stream

To understand value for the patient of a long term condition, such as a cardiovascular disease, a review was completed to identify where the patient engages with the care providers which will enable a value stream map to be created to understand flow and wastes. Figure 7.2.2 highlights the main areas where quantitative data is available to reflect a cardiovascular patient's value stream. The data is analysed and discussed in future sections as indicated in the diagram. The waits between the various parts of the value stream are also discussed when analysing the data. It should also be noted that no end-to-end measure was found within the current system measures in the department of health or the HSC. All measures are from the providers and not the patient pathway which joins together the providers.

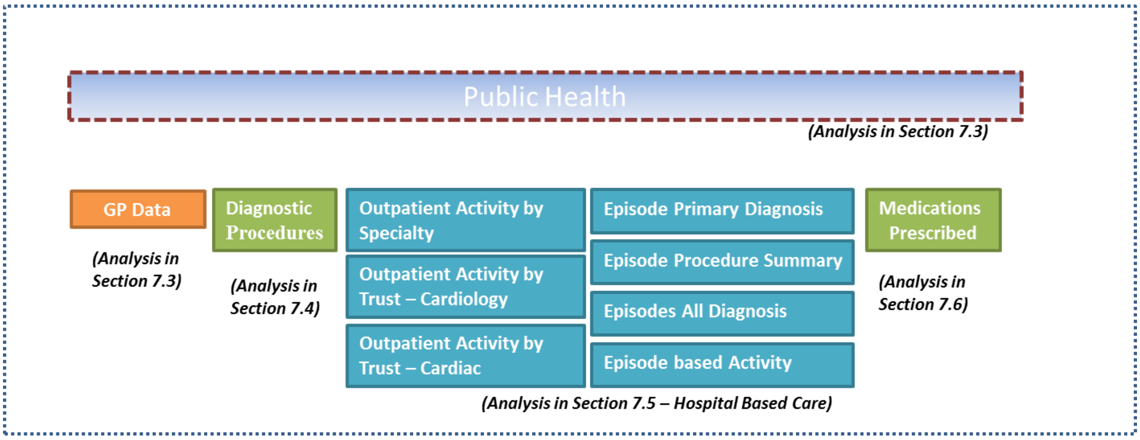


Figure 7.2.2 – Developing a Lean value stream for cardiology patients from available data

GP data is the community based doctor who will assess initial needs and make a referral to the appropriate care. The GP quantitative data is collected through "QOF" reporting which is incentivised through various payments to manage patients within the community. For example GP's are paid additional payments to address specific disease conditions with preventative actions such as monitoring blood pressure. Diagnostic procedures, such as ECG by specialist assessment, are monitored under activity and waiting times targets. Outpatient assessment data and hospital based care are again measured around waits and activity. Medication data is primarily linked to volumes and costs from the procurement organisation of the health service.

7.2.3.1 Gaps in Using a Value Stream Approach

The end to end system value stream map while useful in understanding the flow of patients from GP referral through to treatment however misses a number of key points. The 7.2.3 highlights some missing elements for a Lean value stream map. These will be explored further in the chapters related to that specific stage.

Table 7.2.3 Cardiovascular Disease: Gaps in Value Stream Approach

Unplanned Admissions	Unplanned admission arriving in Ambulances or via Accident and Emergency. *(Identified in quantitative data for hospital activity)*
Domiciliary Care Provision and Care Homes	Many elderly patients with cardiovascular disease provided care outside of the health service in social care. Observational data is often missed and changes often are not fed back to the clinical decision making. *(Identified in Qualitative Analysis with Performance Improvement leaders)*
Palliative Care	End of life of palliative care is often missed from care pathways with care planning for end of life being poorly dealt with. The result is that patient’s wishes are not addressed and in Lean terms over processing of patients can occur as unwelcome treatments are provided. *(Identified in Qualitative Analysis with Manchester End of Life Providers)*
Compliance to Treatment	Individual Patient Responsibility – individual responsibility for diet, exercise, medicines adherence etc. is not included in the value stream. *(Identified in Qualitative Analysis with Medicines Experts)*

7.2.4 Lean Wastes/ Lean Non Value-Add Activities

In section 7.3 to 7.7 the Lean waste identified from the literature review in Chapter 3 will be mapped to the quantitative data activities in the healthcare area for that section. Although this section does not contain quantitative analysis a number of wastes have emerge from qualitative analysis of value. Firstly there is no evidence of patient pathway measurements in the care provision as all measures are limited to specific activities. Secondly there is no evidence of understanding the impact of unplanned admission, as illustrated in figure 7.2.3, of the Lean value stream for cardiology patients or how this could be addressed. Thirdly there is a failure to capture the full patient journeys data in areas such as domiciliary care and care homes which has an impact on the patient value and demand in the healthcare system.

7.2.5 Discussion on the Value Analysis

In summary, understanding “value” in cardiovascular disease can reveal a complexity not found in other industries. To avoid the creation of waste there is a need to focus on the patient as the customer in a Lean reform. The analysis highlights that for long term conditions, such as cardiovascular disease, a value stream can be created that crosses the current providers of healthcare activities and reflects the current patient journey. This is currently not done in Lean healthcare and may have some merit in identifying waste and improving patient outcomes. This has limitations as areas such as unplanned admissions and activities not within the current care providers may have an influence on the patient journey and will need addressed. Additionally the patient will have some co-production elements in value creation in areas such as medication adherence which are not addressed in Lean healthcare literature. The topic of value for the patient is not being fully addressed as care delivery is focused on current process measures predominantly yet there is evidence of a need to consider other measures such as functionality, customer service, patient choices and end of life planning.

The topic of unmet value is not significantly addressed in the Lean healthcare literature of chapters 2-4. Figure 7.5 provides a summary overview for section 7.2.

Summary Points for Chapter 7.2

Challenges

- Patient as the Lean customer – not commissioner or others.
- Commissioning variation across localities
- Currently commissioning activity, not value
- Unmet value in areas such as quality of Life, functionality, customer service, patient choices and end of life planning.

Literature Gaps

- Lean not applied to emerging value based models (Ham, 2016).
- Absence of Lean measures across the cardiology value stream
- Understanding of patient as co-producer of value (for example medication adherence/exercise)
- Addressing unmet value in Lean healthcare

Figure 7.2.3 – Summary Diagram Section 7.2

7.3 Prevention, Primary Care, Community Care and Personal Health

The previous section of the thesis analysed data and evidence from cardiovascular disease patients in relation to value. This began to address the thesis aim of analysing the role of Lean thinking application to integrated healthcare pathways. This was represented in Figure 7.1.2 of the overview diagram of key cardiovascular disease areas. Similarly prevention will have implications on Lean thinking for cardiovascular diseases. Understanding prevention applied to cardiology will assist in addressing the research question of how Lean can be adapted to long term conditions. Prevention however is rarely addressed without considering the General Practitioner (Primary Care) who will be the entry point to healthcare. For this reason this section will analyse quantitative data for prevention and primary care focus areas.

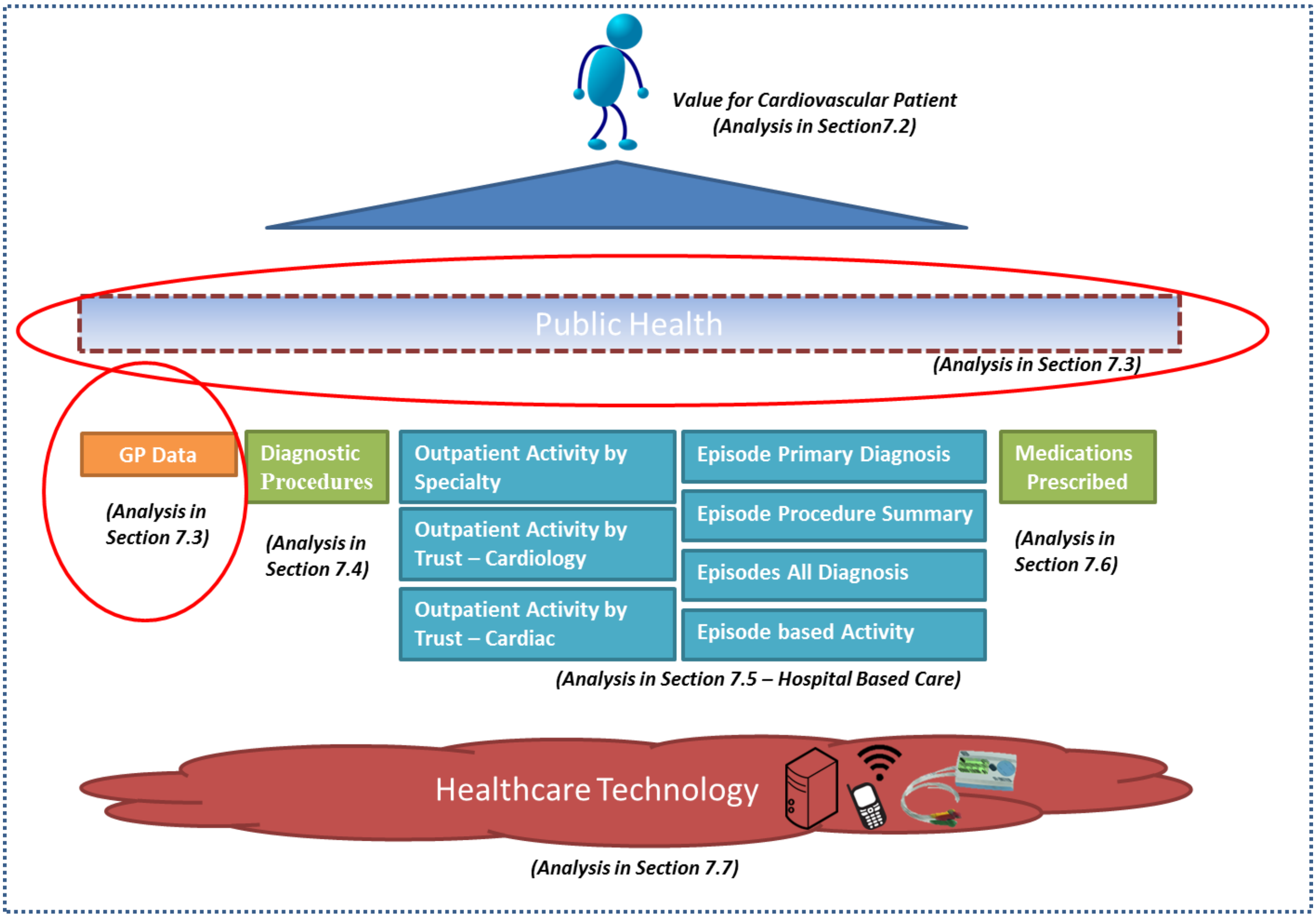


Figure 7.3.1– Cardiovascular Disease Data Set – Focus on Prevention, Primary Care and Community Care

7.3.1.1 Definition of Prevention, Primary Care and Community Care

Prevention, primary care and community care is provided outside the hospital. The public health agency makes reference in its annual report to activities such as screening, public information, engagement and reducing health inequalities as part of its prevention role (Public Health, 2016). Primary care and community care is defined concisely by NHS England as;

"Primary care services provide the first point of contact in the healthcare system, acting as the 'front door' of the NHS. Primary care includes general practice, community pharmacy, dental, and optometry (eye health) services" NHS (2017)

7.3.1.2 The Role of Prevention, Primary Care and Community Care

In progressing analysis for cardiovascular disease it is important to explore prevention prior to early intervention activities. The World Health Organisation highlighted in its "Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases" (World Healthcare Organisation, 2015) that the four areas of physical inactivity, unhealthy diets, harmful use of alcohol and tobacco use are key factors in the prevention of non-communicable diseases. These diseases include cardiovascular disease, diabetes, chronic respiratory disease and cancers. They cause 60% of all deaths. The key point being that many of the deaths are preventable.

7.3.1.3 Future Development of Prevention, Primary Care and Community Care

Simon Stevens (2014) NHS strategy document clearly articulates that preventable illness is widespread and the links to health inequalities are deep rooted. There is a need to address the disease burden fairly and equitably with an approach that considers risk factors for specific population groups (Bauer et al., 2014). When analysing long term conditions, such as cardiovascular disease, the Lean reform opportunities should include prevention and early intervention to improve health outcomes and avoid costs. Despite this there is limited coverage of prevention in Lean healthcare. Some exceptions being linked to preventing errors (Morrow et al., 2012) or preventing falls in cancer patients (Wolf et al., 2013). In both of these cases the prevention is linked to an error or incident being avoided as opposed to prevention of a condition escalation which is relevant to long term conditions. In summary, one can see a desire from healthcare strategy to address prevention but limited Lean healthcare studies addressing this.

7.3.1.4 Prevention, Primary Care Community and Personal Health in This Thesis

The remainder of section 7.3 will analyse the potential for prevention approaches to address Lean healthcare for cardiovascular disease with a focus on public health interventions. This will analyse;

- Current diagnostic interventions in academic and grey papers
- Current measures and data within the NI healthcare system
- What is not measured
- Map the activities against the Lean non-value add activities identified in academic literature in Chapters 3.

From this analysis one can then contribute to answering the research questions of how Lean can be adapted for long term conditions (research question 1) and contribute to identifying methods for health technology to address Lean non-value add activities (research question 2). The analysis will also build some insight into addressing research question 3 where health technology can assist in redefining patient value.

7.3.2 Analysis of Current Interventions Globally in Papers and Grey Materials

Specific guidance from healthcare authorities highlights the promotion of high level programmes and interventions. The following highlights a number of these which are relevant to cardiovascular disease including;

- NICE (UK Based Health Authority and provider standards)
- World Health Organisation
- World Heart Foundation
- US Center for Disease Control and Prevention (CDC)

Table 7.3.1 – Leading Authorities Strategies for Prevention

Organisation	Targeted Policy Areas
NICE Guidance Treatment	Exercise Education Psychological support Self-Management
World Health Organisation	Physical inactivity Unhealthy diets Harmful use of alcohol Tobacco use
World Heart Foundation *(Atrial Fibrillation roadmaps)*	Screening Improving access to preventative medicines such as oral anticoagulants, Reducing the dependence on highly trained experts, Improving capacity for therapy Strengthening Health Information systems.
US Center for Disease Control and Prevention (CDC) (Bauer et al., 2014)	Epidemiology and surveillance to monitor trends and inform programmes; Environmental approaches that promote health and healthy behaviours; Health system interventions to improve the effective use of clinical and other preventive services; and Community resources linked to clinical services that sustain improved management of chronic conditions.

From analysis of these various approaches the key public health inclusion topics with the cardiovascular disease focus are identified as;

- Exercise
- Education (Including Diet, Smoking and Alcohol)
- Psychological support
- Behaviour and self-management
- Preventative medication policy
- The role of public health, treatments and surveillance

These topics will be explored below with a focus on cardiovascular disease and consideration of their contribution to a Lean healthcare approach.

7.3.2.1 Exercise

Analysis of public health strategy documents highlight common acceptance of the need for exercise or activity as a tool for prevention of cardiovascular disease. As an example, NICE Clinical Guidance 67 advises the use of social prescribing referrals to leisure centre and classes with relevant trained staff and exercise instructors. Professional barriers are however reflected in the ACSM health screening recommendations (Thompson et al., 2013) where they consider the weakness of the current advice which insists on various healthcare screening exams and supervised exercise regimes before exercise can be undertaken. The research challenges the lack of evidence behind advice and highlights that the barrier to exercise may be too heavy for patients and significant risk exists for do no exercise while waiting for a perfectly formed review, assessment and clinically monitored exercise regime (Thompson et al., 2013). Mitigating risk through health screens is known to lower the barriers for people of low risk, such as asymptomatic patients and encourage a quicker uptake of exercise. This reflects the idea of prescribing social interventions as an alternative to medication. This will be addressed further in the technology section 7.7.

7.3.2.2 Education (Including Diet, Smoking and Alcohol)

There is a need for education in the prevention phase before getting cardiovascular diseases and also after a clinical intervention to prevent further damage in cardiac rehabilitation groups. Frequently the education will address diet, lowering cholesterol, blood pressure, smoking cessation and alcohol management (NICE, 2017). Public health advice however is not without criticism as evidence suggests that health messages worldwide contradict each other and lack clinical evidence or where there is evidence it can be biased by focusing only on specific groups of people such as those with a baseline high blood pressure (Graudal, 2016). For example the article highlights the focus on reducing salt intake and blood pressure, however low sodium is evident in Yanomami Indians, Brazil and they do have low blood pressure however they also have a lower life expectancy. In this one must conclude that the evidence base for prevention should be questioned and proxy measure of health such as blood pressure levels need to be approached with caution. Similarly other studies provide caution on applying preventative health interventions to asymptomatic people (healthy people) where the studies resulted in new risks due to the therapies (Yusuf et al., 2016). The evidence base behind some public health messages may need to be questioned if focused on value for an individual patient. The nature of public health messages means that advice is generic and will not be of any value to certain people or population groups.

Smoking cessation is a key part of all programmes associated to cardiovascular disease however studies have revealed that the effectiveness is questionable as although they participating in the clinic, only a small amount collected the related medicines which highlights a significant failure (Pagidipati et al., 2016). Separately, research on the use of E-cigarettes to reduce harm from tobacco has some promise but questions around the role of e-cigarettes still remains despite the evidence that it can reduce harm by as much as 95% (Tobacco Advisory Group of the Royal College of Physicians, 2016). Despite this evidence the Northern Ireland Health Promotion agency continues to advocate tobacco removal and not support e-cigarettes (PHA, 2015). From a Lean perspective of value for the patient this may be a questionable approach and lack clinical evidence as it will result less harm reduction as an ineffective strategy. This is underlined by the data showing that current strategy not impacting certain social economic group such as manual workers (Semi skilled, skilled and unskilled) with close to 30% of the population in these groups being smokers (PHA, 2012).

In summary and considering where Lean can be adapted to address waste and where technology could be considered one can find the advice often lacks the evidence which is appropriate to personalised care therefore advice may have limited or no benefit. Goals may be inappropriate for specific patient groups and technology may provide an opportunity to build better outcome based engagement with patients.

7.3.2.3 Psychological support

General prevention and public health advice reflects the area of mental health should be considered as a significant part of cardiovascular patient management with guidance making reference to considering depression anxiety and stress within the operational management of the patient (NICE, 2017). It is known that psychological factors that depression leads to higher numbers of Cardiac events and higher readmissions (Khayyam-Nekouei et al., 2013) The research also highlights a number of studies that link anxiety to cardiac events and outcomes. Similarly the research summarises a number of papers by stating;

> *"They realized that loneliness is one of the important risk factors for patients with heart failure, and the more the patients feel lonely the more severe the heart failure is" (Khayyam-Nekouei et al., 2013, Pg. 104)*

Data is difficult to gather in this area with no open data for existing patients in Northern Ireland. This lack of data does not reflect a lack of relevance but a gap in operational delivery or in Lean terms and unmet value demand. This thesis is not a medical exploration of cardiac interventions or mental health and the exploration will be limited for that reason. The use of technology however may be of relevance to future studies in attempting to quantify the levels of psychological need and potential support.

7.3.2.4 Behaviour and Self -Management

Encouraging self-management is documented on many of the health strategies to reflect a need to move from paternalistic (Topol, 2016) care to a patient leading their own care. NICE guidance, CMG40, recognises that long term care management is important and that providers must put in place pathways to address these as part of cardiac rehabilitation. In the guidance they recognise a role for cardiac services and for the patient's own responsibility. The patient's own responsibility is included in a push towards empowering patients to manage their own health, accessing services and personalising support to match their own need. Self-management APPS are a key creation of the smart phone emergence and the apple store alone had 165K healthcare apps however only about 5% of them have any significant download figures as credibility (Jack, 2016). Some evidence is emerging of networks and peer support being of positive benefit in long term conditions and studies are attempting to understand how networks can assist with better health outcomes and reduced the burden on the health providers (Reeves et al., 2014). In summary, there is an appetite for self-care and self-management expressed in strategic documents (Ham, 2017) but limited data or grey material linked to operation practice that might guide this in cardiovascular disease beyond basic leaflets.

7.3.2.5 The role of Public Health, Treatments and Surveillance

The general practitioner has a role in prevention and intervention after symptoms have been identified. NICE guidance highlights the role of the GP operating with the cardiovascular patients (NICE, 2017). In addition the commissioners have outlined specific areas within their requirements for identifying, treating and preventing the escalation of high risk patients. The interventions include the promotion of lifestyle changes around diet, physical activity, weight management and smoking which will be discussed further in the next section around the quantitative data from the Quality Outcome Framework – QOF (Department of Health, 2017). The QOF measures identify high risk patient groups and define interventions for these higher risk groups with the aim of preventative interventions for cardiovascular disease.

7.3.2.6 Summary

In reviewing the material related to the delivery of cardiovascular disease treatment in the grey and academic publications in the area of prevention, primary, community care and personal health one can see a number of gaps where Lean could be adjusted for long term conditions such as cardiovascular disease. These include the absence of prevention in Lean value stream activities, use of education to inform prevention, absence of psychological support, lack of evidence around self-management and the potential to utilise primary care in the value stream for cardiovascular disease.

Summary Points for Chapter 7.3

Challenges

- Clinical exercise advice creates barriers for patient engagement without considering evidence or risk of doing nothing.
- Social prescribing as alternative to medication not used.
- Exercise beyond the gym is ignored.
- Use of non-specialists clinicians in encouraging exercise.
- Evidence behind preventative interventions needed
- Public health trade offs between harm reduction and tobacco cessation messages may lack focus on patient value.
- Use of self care networks emerging but not part of value stream

Literature Gaps

- Prevention of long term condition escalation not address in Lean healthcare.
- Evidence behind preventative interventions lacking, in particular for healthy individuals.
- Lack of data on psychological impact of cardiology.
- Self Management not understood or its effectiveness.

Figure 7.3.2 – Summary of Lean Thinking Analysis of Current Interventions

7.3.3 Analysis of Current Measures and Data within the System

To gain insight on the prevention, primary care, community care and personal health data with a focus on cardiovascular disease, one must look at the available quantitative public health data and general practitioner data. The quantitative data available of relevance to cardiovascular disease can be divided into two strands with one being linked to public health interventions and the secondly linked to the activities of GP's. The public health interventions will include advertisements or workshops to encourage citizens to eat healthy, walk more or stop smoking. Initiatives will also be commissioned through community groups such as stop smoking groups and research related interventions. The data around these is less easily accessible and appears in various Public Health reports. The GP quantitative data is provided from over 350 GP practices located across Northern Ireland and is structure to reflect the Quality Outcomes Framework (QOF) which are part of the GP procurement returns priorities (Department of Health, 2017).The QOF data is similar to other parts of the UK with some variance between commissioners to reflect local commissioning needs. The large collection of QOF data is available as open data sets and in 2015 there were 57 separate indicator measured and reported on by each GP practice. Each of the indicators have a data set which was comparable to all other GP practices across Northern Ireland for that year. In addition each data set is available over the number of years that indicator has been in use. This has created an extensive publically available big data set.

As the thesis research question is focused on specific measures of relevance to cardiovascular disease the following areas have been targeted. These represent the cardiovascular disease specific measures and the areas identified in section 7.2 as being relevant to cardiovascular disease prevention;

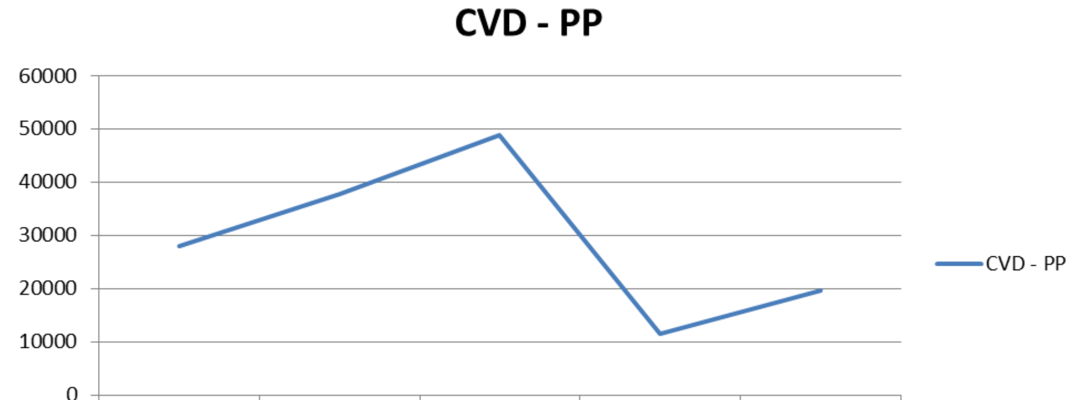
- Cardiovascular disease prevention

- Obesity
- Smoking
- Cardio vascular disease management
- Public health measures
- Summary of available data analysis

Opens source data such as sexual health and female cancer have been excluded from the scope in the analysis due to not being directly related to the thesis topic.

7.3.3.1 Cardiovascular Disease Primary Prevention

The public health focus on cardiovascular disease is targeted at patients with a new diagnosis of hypertension within the age range of 30-75. This excludes patients who are presenting with other conditions such as chronic heart disease and diabetes. The concept of primary prevention is useful from a healthcare perspective as it is using risk factor to identify and target specific individuals. From a Lean healthcare perspective it is also very positive to utilise data for interventions. The data in figure 7.3.3 analysis is presented to cover a longitude view of a 5 year time period to show change and year on year comparisons for cardiovascular disease. The year-on-year comparisons are not currently used within the healthcare system therefore they are unfamiliar with this comparison.



	2011/12	2012/13	2013/14	2014/15	2015/16
CVD - PP	27993	37781	48859	11510	19712

Figure 7.3.3 – GP Longitude Data in Cardiovascular Primary Prevention Activities

What is clear is significant changes in the recorded interventions. This potentially reflects underlying service delivery incentives and disincentives which brings into question the patient value being the driver for change and intervention. Public health agendas are being driven by incentives outside of patient value.

7.3.3.2 Obesity

Obesity is a key focus for cardiovascular disease and many related conditions such as diabetes. Obesity has again been analysed over the same 5 year longitudinal data period that has been used in all other data and one can see that obesity measures are evident for three years before being dropped as a measure from the GP QOF payments. This is despite the measure actually revealing increases in obesity over the period. Obesity has an impact on many health conditions and it is unclear why this would be removed from the measurement. This may reflect a reluctance of public health bodies to measure something that they are not perceived to be making an impact into or a view that measuring the number does not lead to positive action. From a Lean perspective the failure to measure and address this would be a significant concern if this is clearly something that will impact on future healthcare. Equally for the research question 1 about how Lean can be adapted for long term conditions this reflects data on the need to adapt the approach to address issues which are difficult but impact on patient value.

Figure 7.3.4 – GP Longitude Data on Obesity (Department of Health 2014)

7.3.3.3 Smoking

Smoking is also a key focus for cardiovascular disease related conditions such as diabetes, respiratory related conditions and cancers. Smoking data counts the smoking status and at one stage provided a numeric count of smokers with a chronic condition. The measures were changed during the period and moved from counting the number of smokers with a condition to counting the number of patients where the smoking status has been recorded. While it may reflect a degree of moving to a newer method of engagement between the GP and the patient, it could also mask some of the issues of a population not being impacted by public health messages.

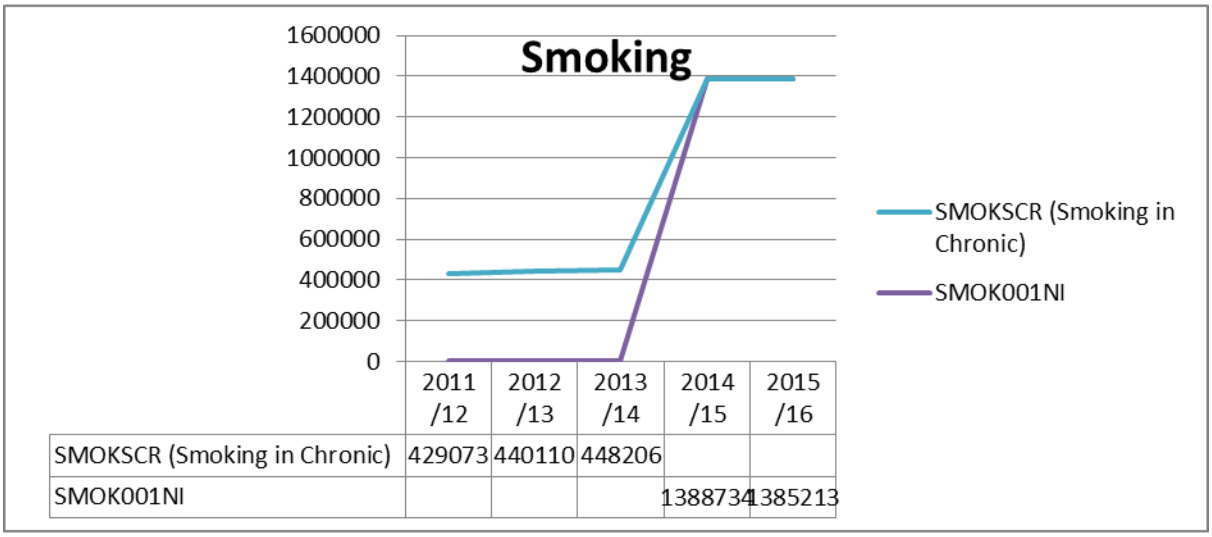


Figure 7.3.5 – GP Longitude Data on Smoking

To explore further what has been measured in the 2013/14 period before the change to the various measures some analysis has been completed to consolidate data. The QOF metrics are designed to incentivise the GP's through a payment associated with each patient. Therefore for every data entry associated to a patient there is an associated payment. For illustrative purposes, there may be a £25 payment for every consultation about stopping smoking. In some cases the incentives are high level and generic to begin the engagement with the patient.

> "The contractor supports patients who smoke in stopping smoking by a strategy which includes providing literature and offering appropriate therapy" - QOF Indicator Definition - Health and Social Care Information Centre

The number of successful counts is the same as the number of GP practices in Northern Ireland therefore the GP is being incentivised to provide a service of signposting support with limited outcome measures. The lack of focus on outcomes leads to considering metrics beyond the GP interventions in public health. The Northern Ireland public health authority report 2105/16 reports that 600 service provider were commissioned to provide stop smoking services.

The stop smoking service have a focus on the following metrics;

- Number with Set Quit Dates
- Number who Quit 4 Weeks Later
- Number not quit at 4 week follow up
- Age
- Sex
- Region
- Deprivation Factor
- Therapeutic Intervention
- Pregnancy Focus
- Referral Type
- Number of Cigarettes
- Previous Participation

The data reveals a number of important factors when considering the research questions of this thesis and in particular the question one about how Lean can be adapted for long term conditions. Firstly the data is largely proxy data such as “setting a quit date” rather than evidence of longer term quitting which in our Lean focus would be required for improved health outcomes or patient value. Secondly the reporting is generally self-reporting which is open to false reporting, misuse or leading to a potential incorrect assumption that a short term improvement will be maintained. The PHA Annual Report and Accounts 2015-16 (Public Health Agency 2016) reports that 59% of patients using a stop smoking campaign were stopped at 4 weeks but it is unclear of the longer term benefit and sustainability of this. The use of proxy information and self-reporting are areas that technology may be able to assist in addressing their weaknesses and this will be picked up in later technology sessions when research question 2 about the use of health technology will be analysed. Also further analysis reveals that 59% of patients stopping smoking as a result of interventions masks a decline in interventions. The smoking intervention level when compared to the populations in a 5 year longitudinal view highlights that although the interventions are providing some level of evidence for success at 59%, the number of interventions have been declining and the volume of patients registered at the GP practice has been increasing. The public health agency messages are therefore masking issues with value for individual patients. Research question 1 questions how Lean can be adapted for long term conditions and a key element here is that Lean must be addressed at the patient level and provide clarity on interventions where agencies may be incentivised to present data that highlights their own value. The high level of reductions in interventions is highlighted below in figure 7.3.6

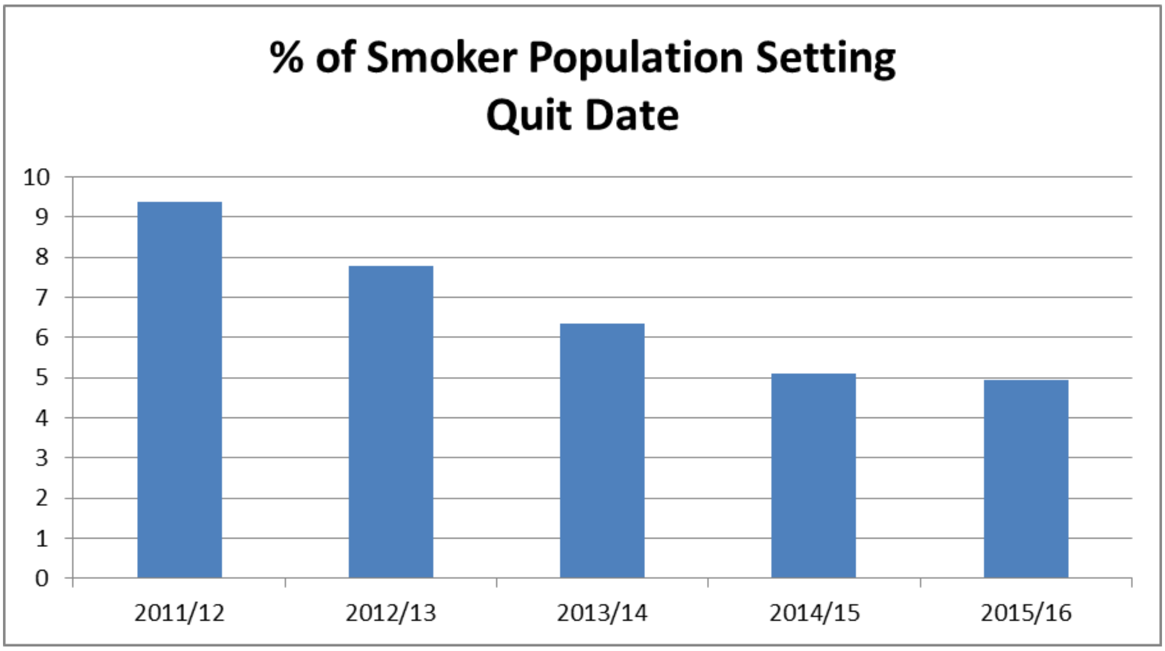


Figure 7.3.6 – Data Amalgamation of Smoker Number and Intervention Levels

The number setting quit dates has decline over the period 2011/12 – 2015/16 with a reduction of 53%. The data appears to suggest that investment is being taken away from prevention interventions which is counter to patient value. To address the research question on how Lean can be adapted the area of prevention should be included and investment or removing investment should be a key consideration. This data was however not visible to most people through the open data sets as it required a combination of a number of data sets which is reflected in 7.3.2 and perhaps highlights an unwillingness of some of the providers to use data for continuous improvement.

Table 7.3.2 – Derivation of the Complementary Data

Data Analysis derived from a number of sources
1. *Quantity of citizens taking part in Smoking Cessation programmes - data-smoking-cessation-database-2015-16* 2. *Population size data sourced from GP Practice lists quantities* 3. *Total quantity of smokers derived from 22% quotation sourced in https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/smoking-cessation-2014-15.pdf.* 4. https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/smoking-cessation-2014-15.pdf

7.3.3.4 Cardiovascular Disease Management

Table 1 in appendix 7 highlights the volumes of patients and some of the GP activities that align with payment incentives (QOF) and the related directives for intervention. AF (atrial fibrillation) is a common heart condition which is monitored due to a link with heart attacks and stroke. Heart Failure is one of the key areas for Cardiovascular Disease and is one of the largest patient groups for readmission into hospital.

As highlighted in table 1 in appendix 7, Heart Failure Patients are monitored and various interventions are encouraged with the GP. The open data available allows consideration of various analytics techniques to reflect on the distribution of patients across the GP Practices. By analysing the heart failure patient data sets one can explore how Lean thinking can be applied to long term conditions such as cardiovascular disease. Figure 7.3.7 data analysis highlights a number of novel approaches, not currently used on the data, to understanding the available long term condition open data.

Pareto Analysis, shown in figure 7.3.7 is a statistical tool used to highlight if large volumes of activity are being taken up by a small number of actors. This is a general tool and not specific to healthcare. This analysis reveals that that 210 (Total 351) of the GP surgeries make up 80% of the Heart Failure patients while volume wise 281 GP practices would be the 80% marker. While it is significant that a smaller number of GP practices (210) are absorbing a bigger volume of the heart failure patients it is not so significant that this would highlight a new approach.

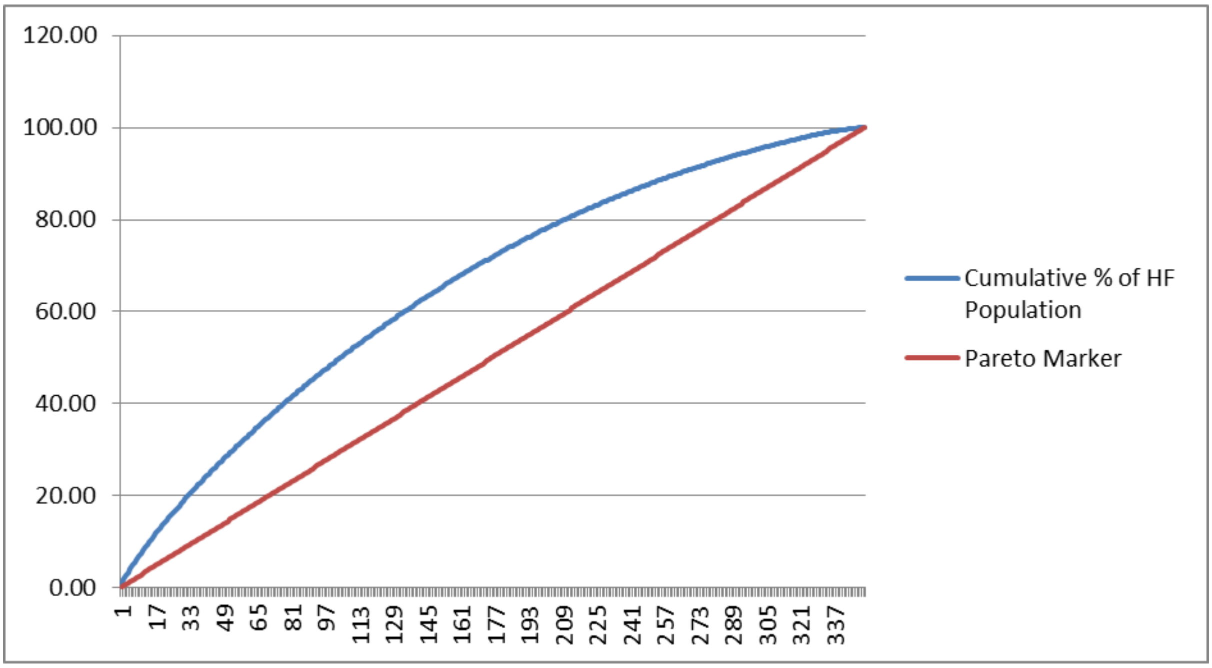


Figure 7.3.7 – Pareto Analysis of Volumes of Heart Failure Patients

Analysing the data per GP practice in more details one finds that the open data records the number of patients with HF per 1000 patients in their practice. This data then allows us to provide a comparison across practices to identify outliers and look for patterns in the outliers. The x axis is a random ID for the practice and what the analysis highlights is that there is 5-10 heart failure patients per GP surgery with a 7.27 average. Outliers exist beyond the 15 patients per/1000 per practice and below 3. This can potentially be explained by geographic difference, age of the population in certain area and many other factors. Analysis of the 5 highest outliers did not reveal a particular focus on a single area of Northern Ireland or a pattern to focus on high deprivation based on the GP practice address. This would not cause you to significantly adjust the approach. The distribution of heart failure patients is reasonable and although there are outliers these can be looked at on a case by case basis, the outliers do not collectively make up an exceptional volume level.

What the data does however highlight is that if the GP practice is dealing with on average just over 7 HF patients and each practice may have a number of GP’s then the volume of patients is a low number as a percentage of their overall workload. This may lead to difficulties in ensuring the GP is up to date in latest good practice and interventions. Research question 3 focuses on how health technology can assist a GP in delivering high value care to a small patient cohort. This will be addressed in section 7.8 and chapter 8.

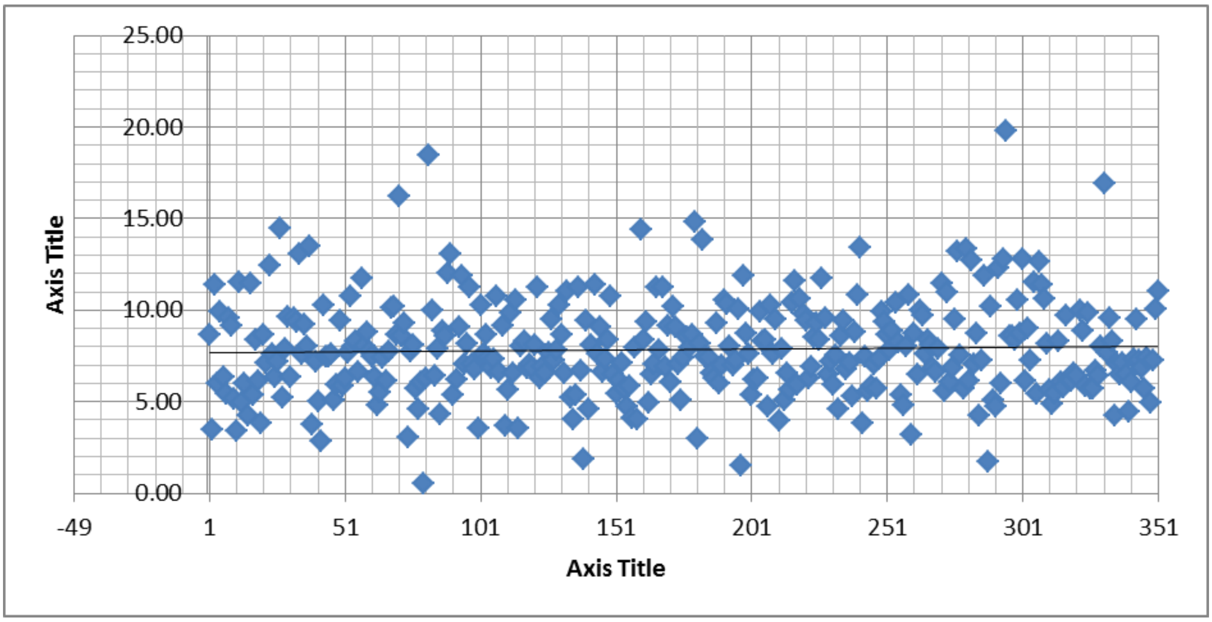


Figure 7.3.8 – Heart Failure Per 1000 patients: Distribution Comparison

7.3.3.5 Additional Public Health Measures

Beyond these key measures linked to the GP, the public health authorities also provide data on strategic prevention target areas including the following;

- Alcohol statistics
- Drugs statistics
- Physical activity statistics
- Obesity and Diet
- Tobacco statistics

The data and statistics in these areas becomes significantly lighter as they represent a sample of 3915 people. While the statistics are proportionate to the population they are still less than a quarter of 1% of the population.

The thesis does not attempt to draw out all of the healthcare messages of the survey but highlight areas that have relevance to the research questions a number of key areas emerge from the 2015/16 survey (Department of Health, 2016) these include;

- Respondents in high deprivation areas eat more chips, processed meat, snacks, sweets/ chocolate, sugary/fizzy drinks, and less fruit and vegetables.
- The proportion of the population who are obese or overweight is highest in the 55-64 age categories, with 74%, with it slightly dropping after this age. The 55+ age group has the highest levels of heart failure with approximately 2/3 being overweight or obese.
- Most deprived areas have 3% higher overweight/obese population than least deprived.
- Smoking prevalence is 23% higher in high deprivation areas than least deprived areas.
- Most deprived areas more than twice as likely to use e-cigarettes 3% v 8%.
- Smoking prevalence is higher in manual jobs than other job categories.

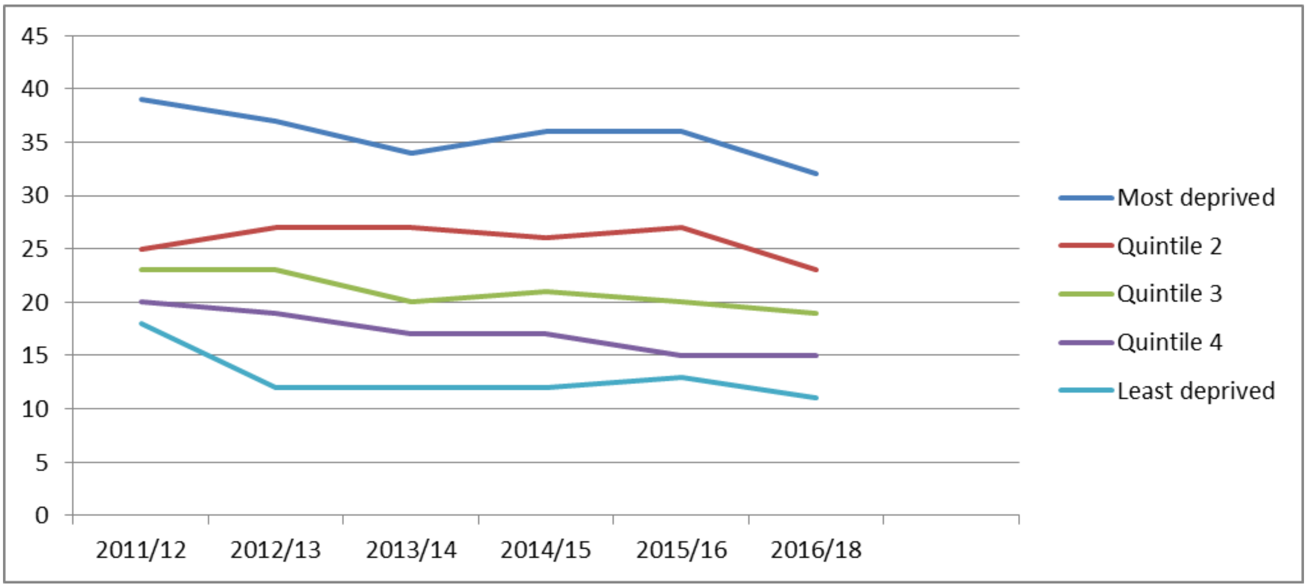


Figure 7.3.9 – Public Health Authority Data (Department of Health, 2016)

In summary and considering the research question one about how Lean can be adapted for Long Term Conditions, analysis has led to the following key areas:

- Public health measures highlight the wide variation in adherence to health prevention activities including smoking, diet and obesity.
- Public health interventions are not significantly impacting certain groups in a population and in particular high deprivation areas.
- Behaviours known to impact poor long term health are known to be substantially worse in high deprivation areas.
- Use of E-cigarettes higher in high deprivation areas and are known to reduce tobacco harm, yet are not promoted by public health.

If Lean value is defined at the patient level then the factors around a lack of adherence, response and success from prevention activities must be addressed at the intervention level. Technology may have a role in identifying waste and personalising interventions which is relevant to research question 2. This could assist in redefining value which is relevant to research question 3. This will be addressed further in section 7.8 and chapter 8.

7.3.4 What is Not Measured

What is not measure but creates value for the patient is an important consideration. Firstly, the long term success of public health interventions is a key gap as although a patient may give up smoking, eat better food and exercise there is limited evidence to link health proxy measures with outcomes.

Impact of Changing Public Health Policies - There is evidence of changing measurements within the GP QOF data so that even within the 5 years longitude data the measures had changed and year on year comparisons were not always possible. This did not necessarily reflect solving a particular issue and moving on to a more important issues but could be perceived as issues of measures being changed for PR purposes and failing to focus on patient value. An example of this was the obesity measures which were rising before being scrapped.

Changes in Intervention Activities - Similarly the data presentation can sometimes mask changes which are important. The evidence above shows that the % of smokers setting quit dates is declining rapidly over the 5 years yet the information in the PHA document highlights the success rate of the few that are stopping smoking. The smaller number of interventions within a growing populations is masked in the data potentially for political or performance management purposes. Similarly poor evidence of impact in areas of social deprivation are masked by averages.

Physiological Interventions – While there is evidence of the negative outcomes of mental health issues such as depressions, anxiety and loneliness there is very little data available to either monitor progress or highlight the success or otherwise of interventions.

Summary Points for Chapter 7.3

Data Gaps

- Long Term Measures of Intervention success.
- Impact of changing public health policies on the value stream for a patient.
- Impact of changes in commissioning intervention to patient care.
- Psychological interventions.

Figure 7.3.10 – Summary of Data Gaps in Prevention, Primary Care, Community Care and Personal Care

7.3.5 Lean Wastes/ Lean Non Value-Add Activities

This section explores the previously defined Lean waste activities in healthcare identified from the literature review in Chapter 3. There is limited academic coverage of prevention in Lean healthcare or the management of long term conditions which makes this section relevant to exploring how Lean could be applied to long term conditions. The quantitative data illustrated in 7.3.3 shows that this is an area of potential relevance when considering the thesis research question two about "can health technology assist in identifying and addressing Lean non-value add activities". The NHS Five Year Forward Strategic Document, (Stevens, 2014) makes a significant point on the cost of not implementing successful prevention strategies as he highlights

> "it makes little sense that the NHS is now spending more on bariatric surgery for obesity than on a national roll-out of intensive lifestyle intervention programmes that were first shown to cut obesity and prevent diabetes over a decade ago"

The Lean wastes below have been identified as being relevant to prevention and primary care in cardiovascular disease patients. These will be relevant in understanding future Lean healthcare models.

Table 7.3.3 – Literature Review Lean Waste Categories Aligned with Cardiovascular Disease: Prevention and Primary Care Focus

Healthcare Failure Area Identified in Chapter 3	***Evidence in Cardiology***
Waiting times	• Delays awaiting GP appointments • Evidence of long delays awaiting referral to outpatients and diagnostics providers result (Data in section 7.4)
Delays	Waiting time associated to referrals is addressed in later section 7.4 (diagnostics) and 7.5 (Hospital Based Care).
Medical Complexity	Increasing evidence of comorbidity appearing in qualitative discussions. Specifically the understanding that clinical advancement is helping people live longer but this leads then to managing multiple conditions into older age. Requirement for ability to manage decision support.
Additional Healthcare Visits	• Additional visits, appointments, procedures and interventions as the service provider is measured based on provision of activity (emerged in Northern Trust focus group). • Patient groups can receive activities which do not add value to them as individuals - medicines for example improve patient groups, not individuals.
Co-ordination of Healthcare resources	• Managing multiple different healthcare groups around a patient (emerged in Northern Trust qualitative analysis).

Stress/overload of staff	• GP appointment times are short and overloaded leaving room for error and omissions. People with dementia find the rush of short visits particularly distressing
Repeated Procedures	• Lack of information in the GP surgery may result in duplicate diagnostic tests and overlapping medication (emerged in medicines qualitative analysis).
Cost	Less relevant as care in community deemed to be more cost effective.
Quality	• Incorrect advice – for example on omega 3 fatty acid. • Maintaining current best practice an issue for clinical guidance of General Practitioner. Inappropriate referrals to hospital as locums or less experienced doctors avoiding decisions (emerged in cardiology qualitative analysis).
Death	Death on waiting lists not measured
Infections	
Emerging from this research and not covered in Lean Healthcare Literature	• PHA messages with minimal impact or evidence of outcomes. – Salt, obesity, exercise. • Cardiac rehab in the community. Best practice but not standard availability across country. • Emerging evidence that genetics may result in some advice having limited or low impact on risks such as blood pressure. • Reference in the NICE guidelines to provide wider package of support which is personalised and builds on what the client can do. • Service provision fails to address individual value as patient may want to trade-off longevity or symptoms against quality of life aspirations. E.g. tolerate pain but avoid side-effects of medications which prevent family engagement. (emerged in cardiology qualitative analysis).

	• Limited use of technology to complement service delivery • The impacts of loneliness on health and wellbeing are well documented as leading to worse health outcomes therefore can be a false economy (emerged in Northern Trust qualitative analysis). • Overfitting of big data (google flu surveillance) • Due to the drive for cost cutting any innovation has focused on either proof of service delivery or reducing costs and no focus on continuous improvement, • Limited use of real time data in community to inform the care needs (emerged in Northern Trust qualitative analysis). • Examples of technology have struggled to define route to adoption

7.3.6 Discussion on the Prevention, Community and Personal Health Analysis

In summary, this section has continued to explore healthcare with a Lean thinking perspective in line with the title of the thesis. The limited evidence of Lean literature in primary care or prevention published papers is in contrast to a search for patient value. Ultimately patient value will be at its highest when avoiding healthcare interventions or avoiding more complex interventions requiring surgery. The analysis highlights areas for considering how Lean can be adapted to long term conditions and specifically cardiovascular disease. A number of technology related issues have emerged which are relevant to research question 2 however this will be covered in section 7.8. Section 8 will discuss research question 3 in more details in regard to data related to technology redefining patient value. The below points highlight the main discoveries in this section with a focus on the research question 1 from the thesis.

The specific points raised are;

1. Prevention of health conditions is absent from Lean interventions in healthcare despite many of the conditions being avoidable.
2. Specific known issues are evident in practice that will make a difference including physical inactivity, unhealthy diets, harmful use of alcohol and tobacco.
3. Specific patient groups *(high deprivation areas)* face a higher disease risk which is referred to as health inequalities.
4. Specific patient groups will perform less well in the known issues of health prevention.

These prevention issues can clearly be applied to new Lean models, however further analysis is needed into the specific interventions which would address the Lean wastes. Additional specific issues around personalisation of care may be identified and address through technology. Finally, analysis of prevention and primary care in cardiovascular disease patients provides an opportunity to consider the aim of the thesis and opportunities for reform and improved healthcare technology. Prevention in particular is largely missing from Lean healthcare and considering this further will provide opportunities to consider new approaches.

7.4 Diagnostics

The previous section of the thesis analysed data and evidence from cardiovascular disease patients in relation to prevention, primary care, community care and personal health. This contributed to the aim of the thesis for analysing the role of Lean thinking application to integrated healthcare patient pathways. In figure 7.2.1 and duplicated in figure 7.4.1 below one can see diagnostic procedures are the next set of activities within the patient value chain. The diagnostic procedure interventions have a series of activities and outcomes which are a key element related to the patient pathway. As the aim of the thesis includes understanding the integrated healthcare pathway it is appropriate to review activities in this area. To continue addressing the research question of how Lean can be adapted for long term conditions this section will review diagnostic activity and identifying Lean wastes within this. It will continue to use cardiovascular disease as an example of a long term condition to provide focus and application.

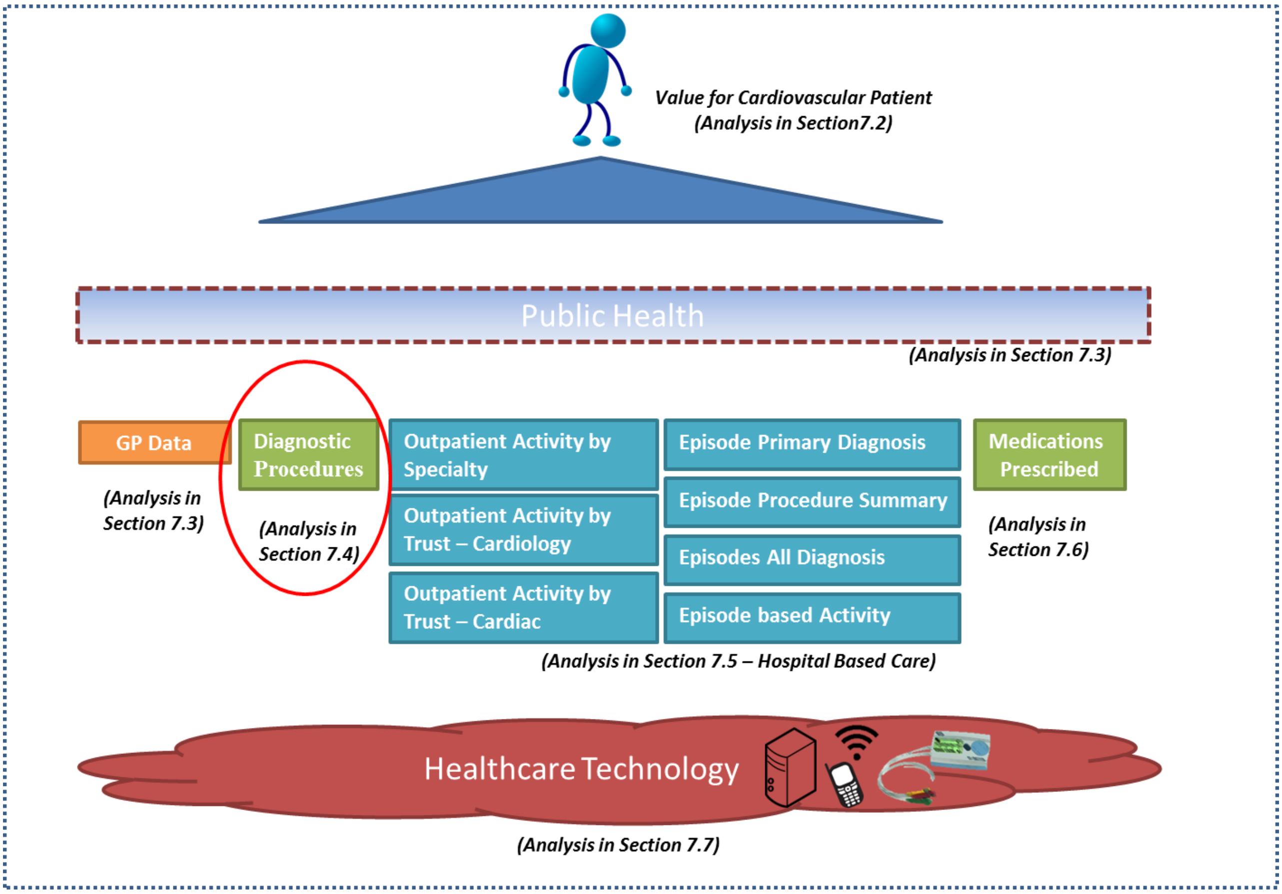


Figure 7.4.1 – Cardiovascular Disease Data Set – Focus on Diagnostics

7.4.1.1 Definition of Diagnostics

To assist in understanding the impact of diagnostic activity on the research question it is important to initially define diagnostics within the context of cardiovascular disease.

The term diagnostic is described in layman's term in the British Heart Foundation communication as "Tests" in their booklet of the same name (British Heart Foundation, 2017). As a further explanation of what diagnostics is, the Northern Ireland waiting times statistics publications provides the following definition "A diagnostic service provides an examination, test, or procedure used to identify a person's disease or condition and which allows a medical diagnosis to be made" (Lynn et al., 2017, Pg. 13).

The types of diagnostics include tests such as those related to bloods, urine, saliva, bodily fluids, and electrical measures from the heart, and images of parts of the body or bodily temperature. The type and purpose of the test will influence where the test could be conducted. The NHS UK Website (NHS, 2017) lists the following types of tests as commonly used for cardiovascular disease;

- Electrocardiogram (ECG)
- Exercise stress tests
- X-rays
- Echocardiogram
- Blood tests
- Coronary angiography
- Radionuclide tests
- Magnetic resonance imaging (MRI) scans
- Computerised tomography (CT) scans

Change is evident in the type of tests used and the scientific advancements reflect a changing landscape of tests. There is long history of using blood biomarkers in diagnostics going back to the 1950 although the specific biomarkers used has changed as scientific evidence continues to develop (Gaze, 2016). From an operational management and Lean perspective, the type of test and the markers used will have quality impacts on decision making and therefore have an impact on the outcomes of decision making.

7.4.1.2 The Role of Diagnostics

To further understand the implication of diagnostics on the research question it is important to understand its purpose or reason within the context of cardiovascular disease. Diagnostic purpose can be varied with common uses including the assessment of clinical risk for a patient, monitoring disease progression, assessing the cause of presenting symptoms in a GP surgery, assessment of symptoms that have led to the patient presenting at the emergency room or therapy monitoring. In each of the cases the purpose is to provide quantifiable data gathered from the patient which can be compared against known clinical thresholds. The diagnostic output data can be used to investigate or confirm prognosis and in the example of heart failure, the uses echocardiogram is used as a method of confirming that a patient has heart failure in line with the commissioner's guidance definitions. Various other functional measures within the diagnosis will also be used to indicate patients who need specific therapies from their GP. Diagnostics relies on quantifiable information rather than a patient opinion but can be used in conjunction to a patients reported symptoms. Diagnostic test are used with caution and clinical judgement as a test result may be explained by a number of factors which may or may not reflect the original assumed condition. The purpose of a diagnostic test is explored later in the chapter. From an operational management and Lean perspective the purpose of the test will influence the value of the test and the impact of non-value activities or waste activities will vary. For example a delay of 10 minutes may be a life or death issue in one purpose or of limited significance in another.

7.4.1.3 Diagnostic Future Development

To understand the diagnostic implication on the research one must also reflect on the emerging solutions to ensure that new innovations which are in the cusp of deployment does not immediately make any findings redundant or alternatively provide data which enhances the position of the research. The scientific and market direction reflect a need to diagnose faster, with more accuracy and move towards a personalised healthcare that recognises the specific needs of an individual. The tailoring of medicines, interventions and therapies is an emerging theme in care delivery and diagnostics can contribute to achieving this. This need to improve diagnostics was underlined in the qualitative analysis with the Cardiology focus group as they were in the process of upgrading the cardiology imaging during the later stages of the thesis development.

7.4.1.4 Diagnostics in This Thesis

With the definition, purpose, types and future direction explained, the remainder of section 7.4 will reflect the common approach of 7.2 and 7.3 of analysing;

- Current diagnostic interventions in academic and grey papers with qualitative analysis
- Current measures and data within the Northern Ireland healthcare system
- What is not measured
- Diagnostic activities against the Lean non-value add activities identified in academic literature in chapters 1-7.

From this analysis the thesis can then contribute to answering the research questions of how Lean can be adapted for long term conditions (research question 1) and contribute to identifying methods for health technology to address Lean non-value add activities (research question 2). The analysis will also build insight into addressing where health technology can assist in redefining patient value which reflects research question 3.

7.4.2 Analysis of Current Diagnostics Interventions Globally in Papers and Grey Materials

As research question one focuses on understanding the Lean non-value add activities it is important to investigate how diagnostics operate and specifically the drivers that will dictate value or waste to a patient. Academic papers and grey papers such as work instructions and best practice guidance provide significant insight on the activities and challenges that are known in the current working practice. The qualitative analysis and in particular the work with the cardiology focus group also provide insight on the use and value of diagnostics. To address the research questions the diagnostic section will require analysis for Lean related issues and cardiovascular patient outcomes. The key points when analysing diagnostics are;

- The purpose of the diagnostic tests
- Waiting for diagnostics
- Location of the diagnostic blood draw, test and analysis
- Comparing laboratory versus point of care testing

7.4.2.1 Purpose of the Diagnostic Tests

Diagnostics covers a wide variety of purposes and patient value will vary depending on the purpose Gaze (2016). From this insight one can derive the impact of potential Lean wastes encountered. In cardiovascular disease there is a long history of using diagnostics at various stages of assessment, intervention and treatment. In current practice biomarkers, vital sign and exercise tests are used at many stages of managing the patient. Increasingly there is pressure to expand diagnostics to prevention and early intervention (World Health Organization, 2017).

Monitoring and identifying the risk of cardiovascular disease to a patient in the early stages of engagement is a key purpose of diagnostics. The identification of risk is a measure which is highlighted in section 7.3. to reflect the desire to intervene earlier and prevent non-communicable disease. A number of risk factors, tests can be used for risk prediction such as assessing plaque formation in blood vessels. This can be determined through cholesterol measures which are associated with being at high risk of cardiovascular disease.

Diagnosing the condition in an emergency department is a second purpose of diagnostics as patients presenting at a hospital emergency may need fast diagnostics tests to determine if a heart attack has occurred or if it is less serious such as heartburn. Qualitative analysis with the cardiology group revealed the complexity of these decisions as biomarkers or ECG tests in themselves do not always provide a definite position. An accurate diagnosis will lead to fast decisions about blood thinning medications and potential surgery to limit the immediate damage to the body, limit the long term damage and protect life or alternatively dismiss the patient as having an insignificant temporary discomfort. Gaze (2016) highlights that 2-7% of patients are inappropriately discharged and large percentages of patients will present at hospital with chest pains which don't require urgent treatment therefore there can be waste in admitting a patient who didn't need treatment. Lean waste can therefore be a Lean quality failure or admitting a patient that doesn't need admitted which is Lean over-processing. These decisions to admit or not can be complicated by heart arrhythmias which are infrequent and blood bio markers that may take a number of hours to present.

Therapy decisions are a third purpose of diagnostics which will determine the appropriate medicine or treatment. Diagnostics can inform primary therapy and the likely impact of a therapy. This can allow patient value to be identified and provided earlier. For those being discharged from hospital or living with cardiovascular disease as a chronic condition, measuring the effectiveness of interventions and disease progression is important. This is to assess if any necessary changes to therapy or intervention are required and to assess the effectiveness of the current medication. For example, heart failure is a common and growing cardiovascular disease condition and reflects the heart not functioning correctly and will be monitored both for the disease progression and the impact of medication to reduce readmission to hospital (Paterson et al., 2014). Similarly the medication can lead to side effects such as kidney damage or bleeding which also needs to be monitored with diagnostic tests.

Table 7.4.1 – Diagnostic Purposes and Lean Implications

Purpose of Diagnostic	Lean Value Implication
Monitoring Risk	• The results are less time sensitive and have a lower quality threshold for patient value. • Transportation waste likely to be higher due to distance from surgery to lab *(emerged in Northern Trust Qualitative analysis).* • Overhead of managing delay experienced by most organisations. • Uncertainty of the turn-around-time will create additional workload for surgery.
Acute presentation – Presenting at hospital or in ambulance with problem symptoms.	• Identification of critical and non- critical symptoms requires faster diagnostics to reduce damage and mortality *(emerged in cardiology qualitative analysis).* • Fast/accurate diagnostics required discharge of patient who needs intervention. Rule out diagnostics. *(emerged in cardiology qualitative analysis).* • High patient and financial cost of inaccuracy in diagnostic test. • The patient's vital signs, symptoms and biomarkers may change during the period after a cardiovascular incident therefore a diagnostic test may have functioned accurately but not diagnose accurately. *(emerged in cardiology qualitative analysis).*
Deciding Therapy	• Diagnostics can inform primary therapy and the likely impact of a therapy. This can allow patient value to be identified and provided earlier *(emerged in cardiology qualitative analysis).* • Evidence of known clinical issues related to medications not addressed. For example drug resistance is not understood at diagnosis leading to Lean waste *(emerged in medicines*

	qualitative analysis).
Monitoring Therapy	• Diagnostics can inform dosage issue and the titration of medication. The length of time to get the titration right is a known waste however getting this wrong is also a waste. *(emerged in cardiology qualitative analysis).* • Diagnostics can identify negative or toxic side effects such as kidney failure due to cardiovascular disease medication *(emerged in cardiology qualitative analysis).*

In summary, one can see that the purpose of a diagnostic test will have an impact on Lean patient value and more specifically will have an impact on the level of waste associated to not fulfilling that value. A diagnostic test delayed by one day in a GP surgery compared to a one day in an emergency room is significantly different therefore in quantifying waste in the delays for cardiovascular disease diagnostics it is important to separate these costs by more than time.

7.4.2.2 Waiting for Diagnostics

The primary waste evident in diagnostics is the classic Lean waste of waiting. The wastes evident however are broken down into waiting time for a diagnostic, Turnaround Time (TAT) for a diagnostic result and reporting time (Department of Health, 2017. These wastes are evident and recorded on the department of health statistics.

The Lean issue however is that many of the measures do not capture the wait from the patient's perspective but from the provider's perspective. The definitions of the waits are documented as;

> "the waiting time for a diagnostic service commences on the date on which the referral for the service is received by the Health Care provider and stops on the

date on which the test is performed.” (Department of Health, Diagnostics Waiting Time, 2016, Pg. 13)

In this definition the patient will have been referred from a GP or other clinician yet the waiting time is not captured until the referral arrives with the diagnostic provider. Additionally the definition stops when the test is completed, yet the interpretation of the test and communication with the referring GP may take additional time. In summary the wait is a provider waiting time and does not reflect patient value. In carrying this thinking across to a Lean value stream map, a more complete measure would involve all activities and waits from the patient’s perspective. Figure 7.4.2 illustrates the difference between the patient view of value and the clinician’s view of value which has been the focus of Lean healthcare literature.

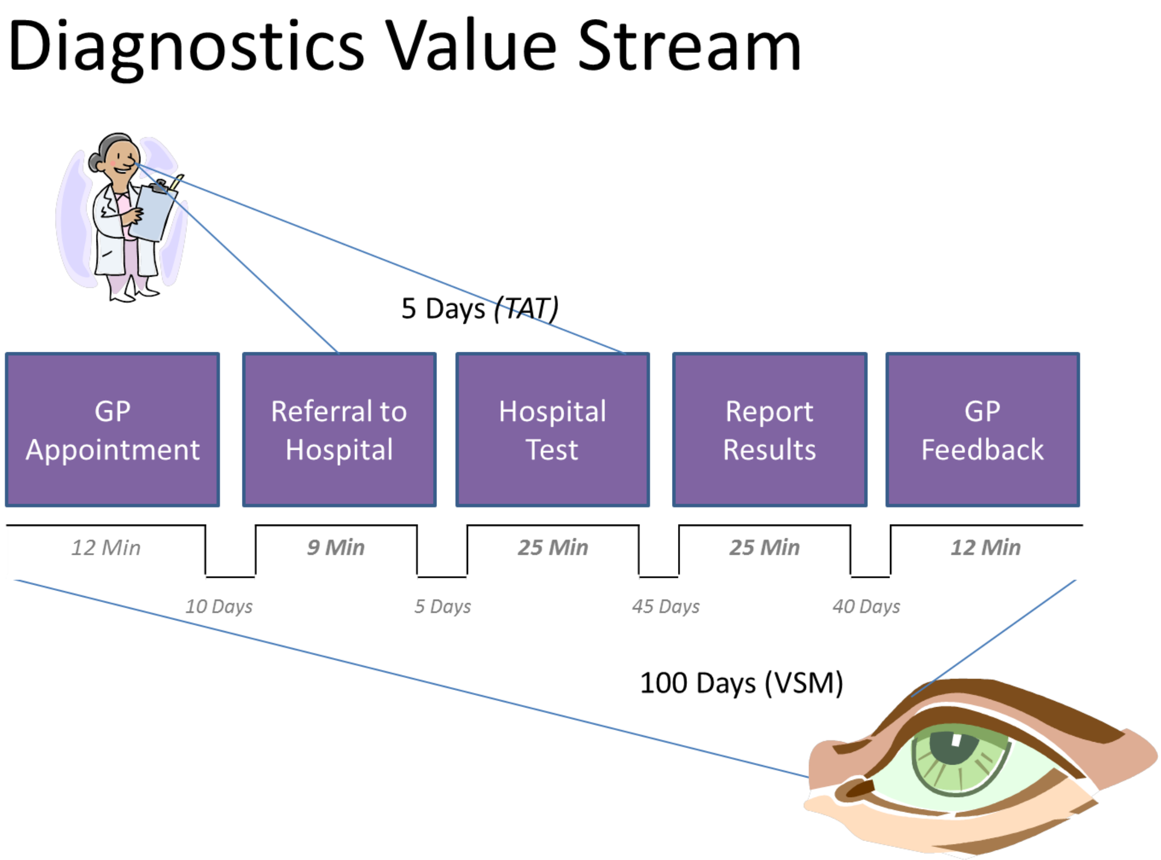


Figure 7.4.2 – Patient Value Compared to Lean Healthcare Literature Lean

In qualitative discussions with healthcare experts to understand the reason behind the reporting time there was a practice of batching cases which is counter to the concept of flow in Lean. The report writing can also be delayed due to the availability of resources with common issues such as busy ward rounds, sickness, holidays, and clinicians travelling to conferences being potential reasons for delays mentioned. The underlying discussion however links back to the system measures being the main focus rather than a patient view of time.

Related to the issues of waiting times which don't match patient value is the area of waiting times targets. The data to be discussed in section 7.4.2 will have been collected with specific targets and measures. There is consistent reference to performance measures which reflect ministerial targets such as

> "By March 2017, 75% of patients should wait no longer than 9 weeks for a diagnostic test, with no patient waiting longer than 26 weeks".
>
> "From April 2016, all urgent diagnostic tests should be reported on within two days of the test being undertaken."

(Department of Health, Diagnostics Waiting Time, 2016, Pg. 13)

These targets have a number of issues which would be in conflict with Lean patient value. Firstly, the target of 9 weeks will not reflect patient value yet be seen as achieving success if met. Secondly the target assumes a further failure for 25% of the patients beyond the 9 weeks, therefore even within the flawed 9 week target; 1 in 4 people will receive a substandard performance from the patient perspective. When looking at the number of patients waiting for echocardiography in Northern Ireland there are over 10K patients waiting which means that over 2500 patients will receive substandard performance even within a non-patient value measure of 9 weeks. The implication of this for management is that a service can fail so many patients and still be deemed to be successful. Thirdly, a system which target a turnaround time of 2 days is not working on any concept of Lean continuous flow as this will mean that they are batch processing the diagnostic tests. This is generally known to attract errors and waste.

Table 7.4.2 – Understanding the Value Stream Activities and Waste

Typical Value Stream Linked to Diagnostic Tests From the GP	Lean Waste	Value Activity
Waiting time to see the referring GP	✓	
Activity time of seeing the GP		✓
Activity time of writing referral		✓
Transportation of Referral (increasingly moving towards electronic referral but not universally)	✓	
Waiting time to get test administered	✓	
Activity time of processing the referral to the health providers system		✓
Activity time of triaging or prioritising referrals		✓
Activity time of completing the test		
Waiting time for the analysis and results of the test	✓	
Activity time for the analysis and for the report to be written		✓
Waiting time for the report to be received by referring time	✓	
Waiting time for appointment for the patient-GP discussion on therapy or referral	✓	
Activity time for patient-GP discussion on therapy or referral		✓
End		

The delays are not without health outcome cost as unlike a piece of equipment waiting for the next activity within a production line a patient's condition may be deteriorating therefore waiting can lead to an exacerbation of a condition or result in an unplanned admission to hospital or death. In both cases there is a health outcome cost and a financial cost.

7.4.2.3 Location of the Diagnostic Blood Draw, Test and Analysis

In the above example the patient was in the GP and the test was at a separate clinical institution. This is not the case in all diagnostics and three factors have to be considered in understanding diagnostics for cardiovascular disease prior to making any assessment of how health technology can address Lean non-value add activities in line with the research questions. The three factors are;

- Location of the diagnostic blood/fluid draw
- Location of the test and
- Location of the analysis

The blood draw applies only to diagnostic tests requiring a urine or blood sample as this can be provided at a different location from where the test is completed. In cases of electronic or imaging tests these are completed at the same location. Understanding this is needed as the separate activities and the gap between them is of interest in a Lean value stream review.

Table 7.4.3 highlights the key considerations and implication on Lean being adapted for Long term conditions, identifying Lean Non-Value add activities and opportunities to redefine Patient Value.

Table 7.4.3 – Redefining Patient Value in Diagnostics

Diagnostic Component	Location	Implication on Research Questions
Location of the Blood Draw	• Home Based • GP • Community • Pre-Hospital/Ambulance • Emergency Department • Outpatient • Inpatient	• Transportation waste to laboratory. • Evidence of Lean waste of errors and defects as samples sent in inappropriate containers from GP. Errors revealed in discussions. (Qualitative Interviews - Medicine Focus Group) • Examples of where standard operating procedures state that sample is not to be sent for patients with certain existing conditions but these are still sent. Non-value based demand. Errors revealed in discussions. (Qualitative Interviews - Medicine Focus Group)
Location of the Test	• Point of Care Testing such as in the community by the nurse, home based by the patient, in the GP surgery, bedside testing by the clinician or in the physician's office, • Pre-hospital/ambulance • Lab in Emergency Department • Central Lab	• Diagnostic good practice seen as high volumes machines with batch processing. This may be in conflict with general Lean best practice approaches. • Limited use point of care testing with the gold standard of testing still being seen as the lab. (Qualitative Interviews - Northern Trust Focus Group) • Potential for over processing of diagnostics as decisions to treat or not treat may not require full analysis. Rule out and rule in

		diagnostic tests with lesser thresholds may be sufficient with local simple testing with lower quantification thresholds.
Location of the Analysis	• Immediate POC feedback • Report writing by expert • Validation and Quality checking - • Obtaining the results	• Point of care testing both in small machines and lateral flow test may provide some alternatives to a need for written test results (Qualitative Interviews - Northern Trust Focus Group) • Academic evidence of decision bias by clinicians when interpreting ECG results after they find something early that makes sense. • Machine learning Technology available to reduce the need for clinical analysis. • Evidence of lean value streams with long delay wastes between the diagnostic test and the reporting. • Potential for over-processing of analysis. • Analysis relies on standard approaches and reading of visual clues which can be open to human error even with experienced clinicians. Examples of clinician bias (Bond et al., 2014).

In summary, the analysis highlights a key issue of the separation between blood draw, test and analysis as being factors which will influence the quantity of lean waste and the value of improving turn-around times.

7.4.2.4 Comparing Laboratory versus Point of Care Testing

The analysis reveals a movement toward point-of-care diagnostics which is diagnostics at the side of the patient instead of in a lab. In some cases this will be a small machine or device which can be used to analyse blood, electronic signals from the body. In other cases it may be dip tests where a fluid of the body reacts to reveal a diagnostic decision. Commonly seen examples include pregnancy tests, diabetes blood tests, heart rate monitors, blood pressure cuffs, temperature measures and blood oxygen tests.

Logically from a Lean perspective moving diagnostics closer to the patient has a potential to remove waste. It is not straightforward and introduction of this is not without challenge. Table 7.4.4 highlights the pros and cons of this type of diagnostics and reflects qualitative analysis with the Northern Trust focus group and cardiology focus group.

Table 7.4.4 – Comparing Point of Care Test Advantages and Disadvantages

Positives of Point of Care Testing	**Negative of Point of Care Testing**
• Simple analytic handling • Faster results • Reduce pathology access barrier • More frequent tests for building longitudinal profile of the patients • Lack of Benefit - UK study of 1728 ED patients found that changes in patient management came 74 minutes earlier	• Workload in community • Standard Operating and Error rate can be more difficult to control • Incompatibility of different tests and devices • Cost • Storage of results • Coefficient of Variation (CV)

however it did not impact the clinical outcome of the length of stay in ED. (Kendall J – point of care testing: randomised controlled trial of clinical outcomes - 1998) • Cardiac markers - 263 patients with chest pain – Collinson et al – lower length of stay in emergency department and in hospital. • POCT lateral flow test and similar can be cheap.	• More Hardware required per test • Maintenance and control of testing devices can be an issues • Single assay cartridge used with dedicated equipment • Low volume of tests completed per staff member • Lab machine can complete high throughput analysers with large volumes of tests and low TAT which make the use case in a hospital more difficult due to the efficiency of the alternative. • POCT quantification is an issue with the quantification of biomarkers may not be available.

In analysing the mix of views on the use of point of care testing we find an ever growing number of devices will make point of care testing more available in the future. Quality and control however remain a large issue and the business case of moving the role of diagnostic tester to the front line roles has not been resolved yet as this will have an activity cost.

Not largely covered above is the emerging collection of wearable devices on the market that allow quantification of the electrical signal from the body in terms of heart related signals. At the time of writing there was a lot of evidence of sporting and hobby interest in vital signs measures but largely this has not yet crossed over into clinical relevance yet. This is a changing space and many of the gadgets on the consumer space are attracting the attention of the FDA who has avoided regulation of the area as the majority were used for recreational purposes. Increasingly the technology firms have sought out FDA approval to make their device clinically relevant and create a differentiator or barrier from competition. An example of this is the American based company AliveCor which provide medical grade monitors which communicate with the mobile phone and provide ECG data (AliveCor, 2017). It has then targeted specific clinical conditions such as atrial fibrillation which can lead to strokes. Mobile clinical grade equipment will be part of the future offerings but the quality and consistency of the information is still questionable in most cases and largely not accepted by healthcare professionals. Qualitative analysis with the cardiology focus group revealed the clinicians were dismissive of hobby grade wearable heart rate monitors and point to grey literature studies than show comparison between various device highlight the large variance in measures however there was a number of products emerging that they found interesting and were exploring due to the speed and mobility of the devices.

7.4.2.5 Summary

In reviewing the delivery or cardiovascular disease related treatment in the grey and academic publications in the area of diagnostics one can see a number of areas where Lean and technology can be used to adjust care delivery. Diagnostics is an area that has been covered in Lean healthcare reform work (Dyas et al., 2015) but largely it has been in isolation from the complete patient pathway and often within the boundaries of the current measures for a specific provider. The Lean pathways frequently explored methods to accelerate the current processes rather than consider value from a patient's perspective. What is revealed above is that the overlaps between the organisational silos can often reveal Lean patient wastes which are not addressed such as the time taken to complete the diagnostic from referral until receiving the analysed results.

Thesis question 1 asks the question about "How Can Lean be Adapted for Long Term Condition". The analysis of diagnostics reveals a patient presenting in a hospital emergency room can be difficult to diagnose (Gaze, 2016) for this reason diagnostics does not naturally fit within a sequential Lean flow as diagnosing is essentially fault finding rather than building through a series of steps. Errors in fault finding can lead to fatal consequences or increase the medical complexity for a patient with an undiagnosed condition.

The analysis of diagnostics does however reveal elements where Lean can contribute to long term condition patients. The waiting times and series of measures have been divided up in a manner that does not reflect patient value but reflects organisation silos as the measurements start with the organisation and not the patient. In addition the performance targets do not reflect patent value (9 weeks) therefore there is no incentive towards improvement. Additionally the measures reward the providers when they have failed 25% of the patients which again has no basis for a Lean patient value centred organisation. These areas have an opportunity to rethink how Lean can be applied to long term conditions.

More traditional Lean wastes in healthcare are also represented in waiting for a test to be started, waiting for the test to be reported on and the turn-around time of a lab test. These lead to wastes of waiting and effort managing waits, answering patient queries and administering a waiting system in surgeries. The batching of tests and reports are evident in the processes through the sending, administering and reporting of diagnostics which challenge Lean flow. Uneven resourcing of tests were also revealed in qualitative interviews as the transportation to the labs from the GP is available Monday to Friday therefore tests required over the weekend can often result in an unnecessary A&E visit or longer wait.

Diagnostics can however result in Lean value delivery as the diagnostics of blood and vital signs which reflect the personalised position of an individual patient and determine the appropriate interventions and therapies provided at the right time and in the right quantity. In research question 2 the question asks if health technology can assist in identifying and addressing Lean non-value add activities. One can see that technology is already emerging in use for risk scoring systems, decision supports and automated ECG interpretations to attempt to assist in managing the complexity presented and the tools aim to reduce the risk of inappropriate discharge as part of a clinical assessment.

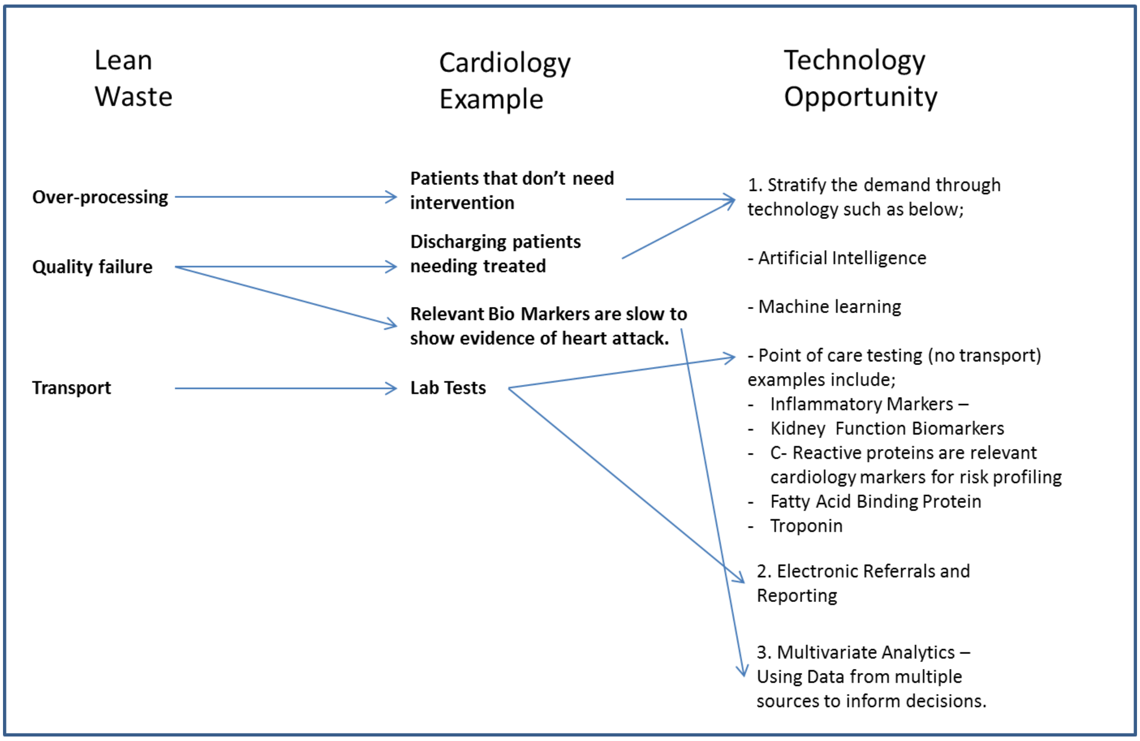


Figure 7.4.3 – Lean Diagnostic Wastes and Technology Opportunity

7.4.3 Analysis of Current Measures and Data within the System

This section will present the quantitative data from diagnostics for cardiovascular disease. This relates to big data open source information from the 5 Northern Ireland Health and Social Care Trusts. The diagnostic data is reported under two key methods with the first being activity levels focused and the second being waiting times. For the purposes of this thesis the quantitative analysis has focused on the waiting times data due to the link with Lean waste and often the volumes of waiting tests provides a summary of the overall activity demand levels. The waiting times adhere to various rules and procedures around the counting of waits. This thesis will not dwell on these rules as they have a limited contribution towards understand Lean value from a patient point of view and reflect hospital administration procedures. Waiting is one of the seven classic wastes in Lean although the “seven wastes were originally for manufacturing. However, this also has application in many types of service” (Bicheno and Holweg, 2016, Pg. 21).

A referral will be made to the specialist provider for a specific test to assist the clinicians in diagnosing the patient. Qualitative discussions with experts have revealed the terms “rule out” and “rule in” to indicate that a diagnostic test can be to confirm that the patient doesn’t need treated (rule out) or to confirm they do need treated (rule in). A patient who has been referred for a diagnostic test will be recorded within the Health Trusts ICT system and the health trust will be required to report on the numbers of patients waiting on a quarterly basis. Diagnostic waits data from all the hospital trusts will be available and presented in the following manner to reflect groupings of patients waiting for different periods of time.

Row Labels	Sum of Total	Sum of 0-2 days	Sum of 3-7 days	Sum of 8-14 days	Sum of 15-21 days	Sum of 22-28 days	Sum of >28 days
CARDIOLOGY - ECHOCARDIOGRAPHY	260548	206677	28152	12043	4799	3751	5126
CARDIOLOGY - PERFUSION STUDIES	12518	3687	4919	2554	1002	319	37
(blank)							
Grand Total	**273066**	**210364**	**33071**	**14597**	**5801**	**4070**	**5163**

Figure 7.4.4 – Example of a Diagnostic Waiting Time Report Data

The quantitative data analysis big data sets have been created from this reported information across all of the health trusts over a 5 year period. Qualitative interviews have revealed limitations within the data as a patients will appear on more than one quarterly report for the same test if their wait is for longer than a quarter of a year therefore there is no ability to calculate the demand across the whole year with this data. Secondly a small number of patients will be referred and the diagnostic test will be completed before entering a waiting list therefore their activity will not be visible. Finally the emergency procedures can have an impact on data as emergency slots can be taken and have an impact on available resources for waiting patients.

The quantitative data for diagnostics is substantial and beyond the scope of this thesis to analyse all of this. The following diagnostic tests have been selected due to their relevance to cardiovascular disease as outlined at the beginning of section 7.4. This reflects the NHS UK cardiovascular diagnostics commonly used for cardiovascular disease (NHS, 2017).

- Ambulatory ECG monitoring (24 hr holter)
- Cardiology - echocardiography
- Cardiology - perfusion studies
- Cardio-respiratory exercise testing
- Computerised Tomography
- Electrocardiograms (standard and 12 lead)

- Exercise tolerance testing
- Magnetic Resonance Imaging
- Plain Film X-rays

The diagnostic waiting times data brings together approximately 17000 data points over the 5 years with a correlation to cardiovascular related diagnostics. This was filtered from 97755 data points from all diagnostics recorded back to 2008. One constraint is that the open source data does not highlight a diagnostic tests purpose therefore a test may be of relevance to a number of conditions such as a cardiovascular disease and respiratory illness. In the case of a plain file x-ray, a multitude of illnesses and injuries will use a similar diagnostics test with many of them unrelated to cardiovascular disease.

7.4.3.1 Cardiovascular Disease Diagnostic Waiting Time

For the purposes of the thesis it was important to analyse the volumes of waiting days and shifts across the longitudinal data. Moving to a point where it would be possible to quantify the waste being created. In the below diagram the data has been used to calculate the waiting time for cardiovascular disease relevant diagnostic tests as a total waiting days for the patient cohort in the system. By doing this we begin to build an understanding of "cost" of waiting on the patients. In addition by doing this we allow comparisons across the time period which is not possible when just looking at the particular category of wait they are in.

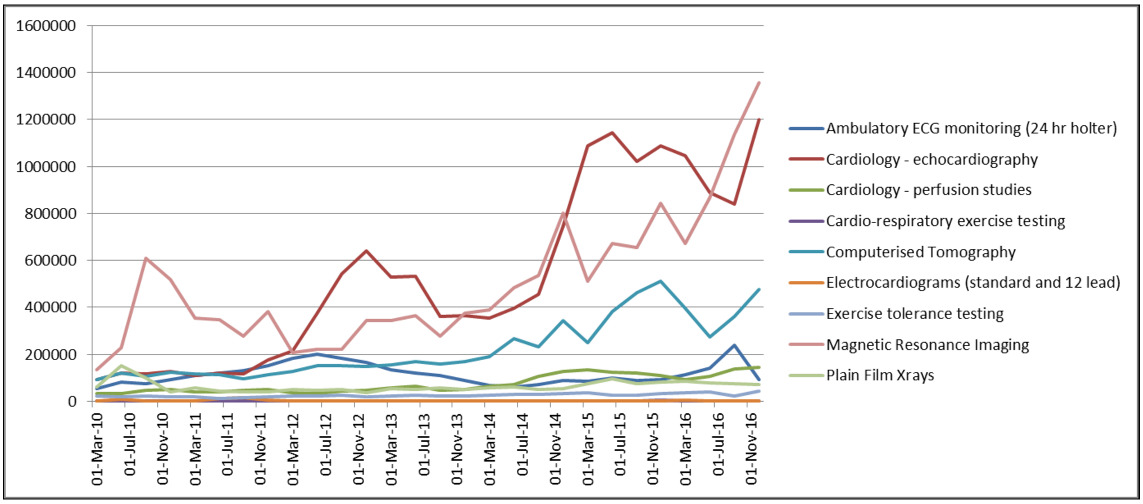


Figure 7.4.5 Graph – Number of Patient Days Waiting for a Cardio Vascular Related Tests *(Y axis reflects patient wait days)*

This data analysis is calculated by multiplying the current volume of referrals in the system that are waiting on a diagnostic test by the mid-point in the waiting time category that they have been allocated to. For example 1043 people may be recorded as waiting 0-6 weeks therefore a calculation will use an estimate of 21 days as a mid-point and the actual number of people waiting to estimate that patients are waiting 21903. This calculation is then done for all waiting time categories, time periods and types of test to provide the above analysis.

This has limitations as there is no way of understanding within the open data if the data points do average around the mid-point however it is a useful measure to compare across the time periods in a manner not currently used in the system. There was an expectation that presenting this material to the focus groups would attract criticism or defensiveness however this was not the case and the groups largely reflected that this was useful analysis and that the data visualisation reflected what they perceived to be the case but did not have data analysis available to them to reflect this.

What the graph clearly recognises is that the number of waiting days in the system is growing. In Lean, waiting is a key waste which adds no value to a patient. This therefore is indicative of a growing waste in the system and movement away from patient value. In December the largest waiting days are;

- 1.3m patient days waiting for MRI’s
- 1.2m patient days waiting for Cardiology – echocardiography
- 0.5m patient days waiting for Computerised Tomography

This data reflected the whole of Northern Ireland but the data is from 5 HSC trusts. To analyse more granular details it was important to consider comparisons across the service provider health and social care trust to understand variance and best practice.

7.4.3.2 Comparisons across Healthcare Providers

Figure 7.4.6 focuses on the Ambulatory ECG Holter Monitor test to allows a comparison across the 5 Health and Social Care Trusts.

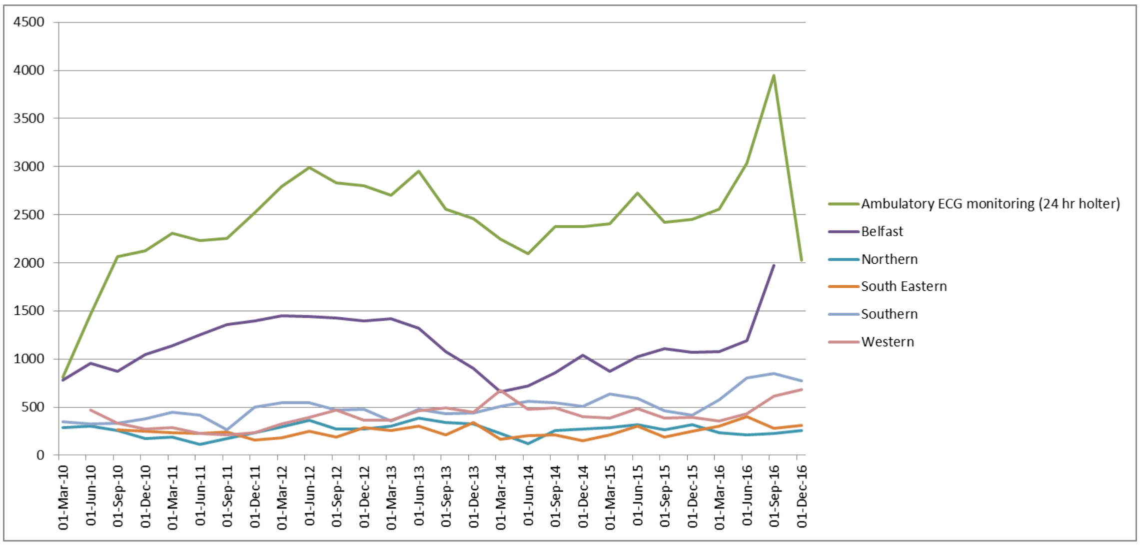


Figure 7.4.6 Graph – Number of Patient Days Waiting for Ambulatory ECG Monitoring (24Hr Holter) (*Y axis reflects patient wait days)*

The rise in diagnostic waits can be indicative of a problem which has caused a spike in the number of waits or it can reflect a change in the overall system creating a spike in demand. For example a change in payments for the GP to incentivise the patients to take a holter monitor test or a change in clinical guidance from NICE can result in a spike in demand of a diagnostic test. The diagram also highlights that the vast majority of the patients waiting tests are with the Belfast Trust. Approximately 47% of all tests during the reporting period have been with Belfast.

One can see is that there is opportunity to understand the wastes further by breaking down the content and use longitudinal data to understand the overall system drivers. There are however limitations to understanding the data and it is likely that Lean tools such as visual management would aid these discussions and future interventions. There are also data reporting gaps (Belfast December, 2016) that would have been missed without granular data therefore risks of data completion need to be highlighted.

7.4.3.3 The Need for Contextual Awareness in Longitudinal Quantitative Data

The diagnostic waits for Echocardiography, which is one of the largest volumes of Diagnostic tests specicially for Cardiovascular Disease related conditions, is available in figure 7.4.7.

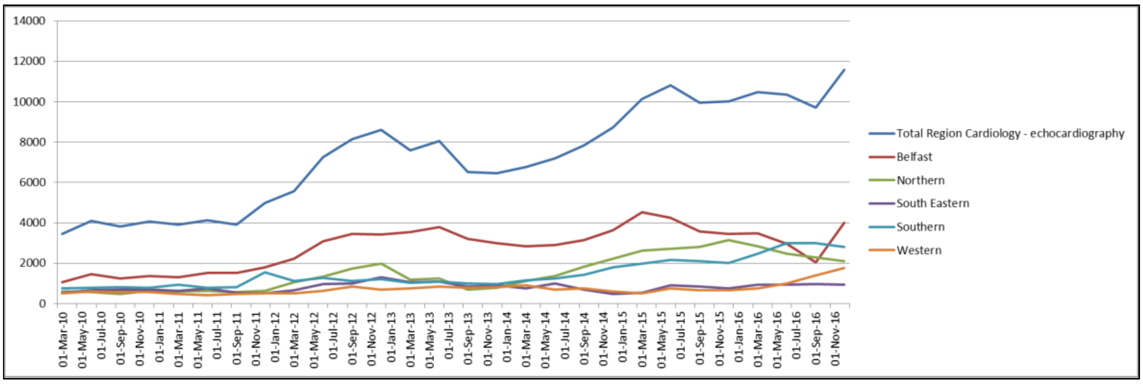


Figure 7.4.7 – Number of Patient Days Waiting for Echocardiography (*Y axis reflects patient wait days)*

Belfast is a largest volume of the tests, but it is a lower percentage with approximately 38% of the test waits being in Belfast. Considering that the majority of patients live in Belfast this underrepresents the patient populations. Again reflecting a need for granular data and comparisons against the trusts own performance rather than another trusts. As the Belfast trust has a much higher throughput of patients it would be reasonable to claim that the patient value is higher there are less patient wait days evident.

From the Lean healthcare perspecitive the issue to absorb if that blunt measures that don’t take into account the nuances of specific localities will miss critical factors related to improvement and patient value.

7.4.3.4 Analysing Numbers of Patients

The ECG length of wait in figure 7.4.8 reflects an alternative analysis method providing detail on the number of patients waiting for a defined period of time for and ECG diagnostic test. What is noticeable is the peak after the 9-13week period. While it is difficult at face value to note any reason for this it is known from publications discussed earlier in this section that there are 9 week targets for diagnostic tests. It would be reasonable to question if some of the drivers for addressing waiting times targets are therefore reactionary to 9 week performance targets rather than patient value. The system is effectively incentivising the HSC trust to put less priority into the 25% who would miss the target within their own performance target. The deductive logic then follows that there is a potential negative implication to the patient value if performance targets are being prioritised above patient value.

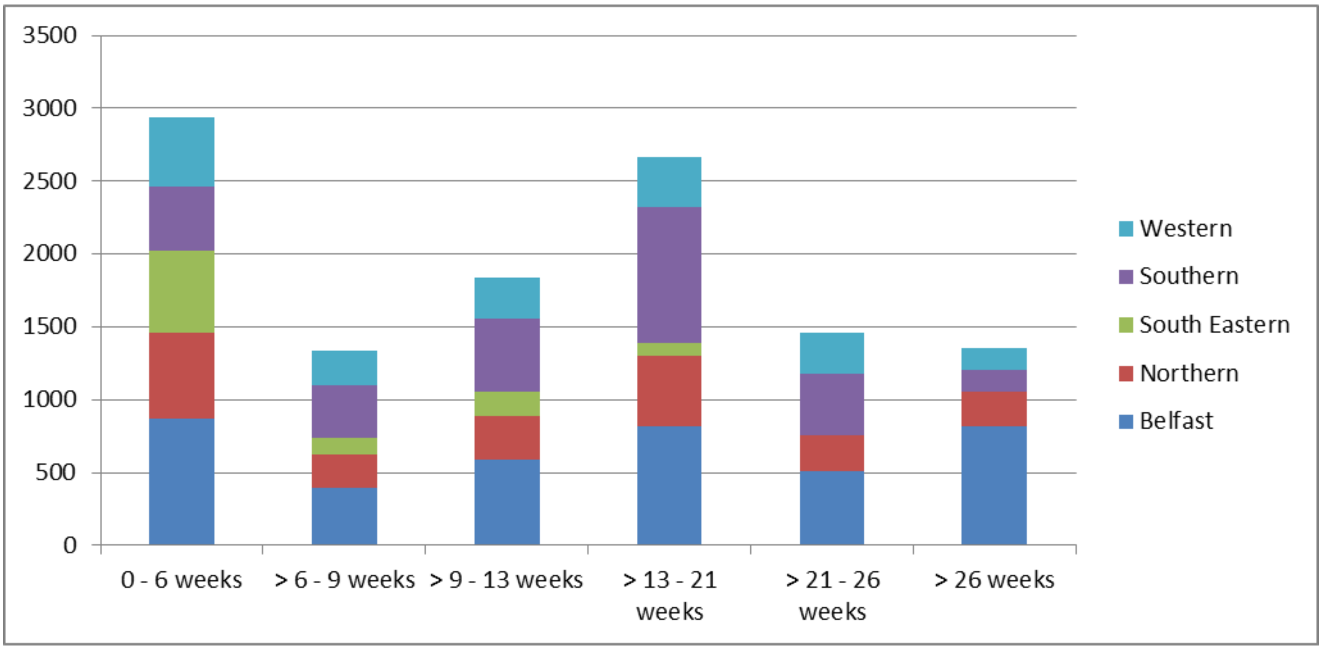


Figure 7.4.8 – Number of Patients Waiting for Echocardiography – HSC Trust Breakdown (*Y axis reflects number of patients waiting)*

The Lean potential revealed is that visual management tools may pay provide an ability to monitor system drivers that do not reflect patient value and adjust practice accordingly. Using the same data but analysing it slightly differently from a summation of the time buckets to a summation of the Health and Social care trust provider. One can see significant performance differences within trusts. The implications for Lean being standard work and lessons learned from one trust could be applied to other trusts. Within Lean, the scientific management principle is a key element with Plan-Do-Study-Act being reflecting a continuous learning approach which is a key element of improvement.

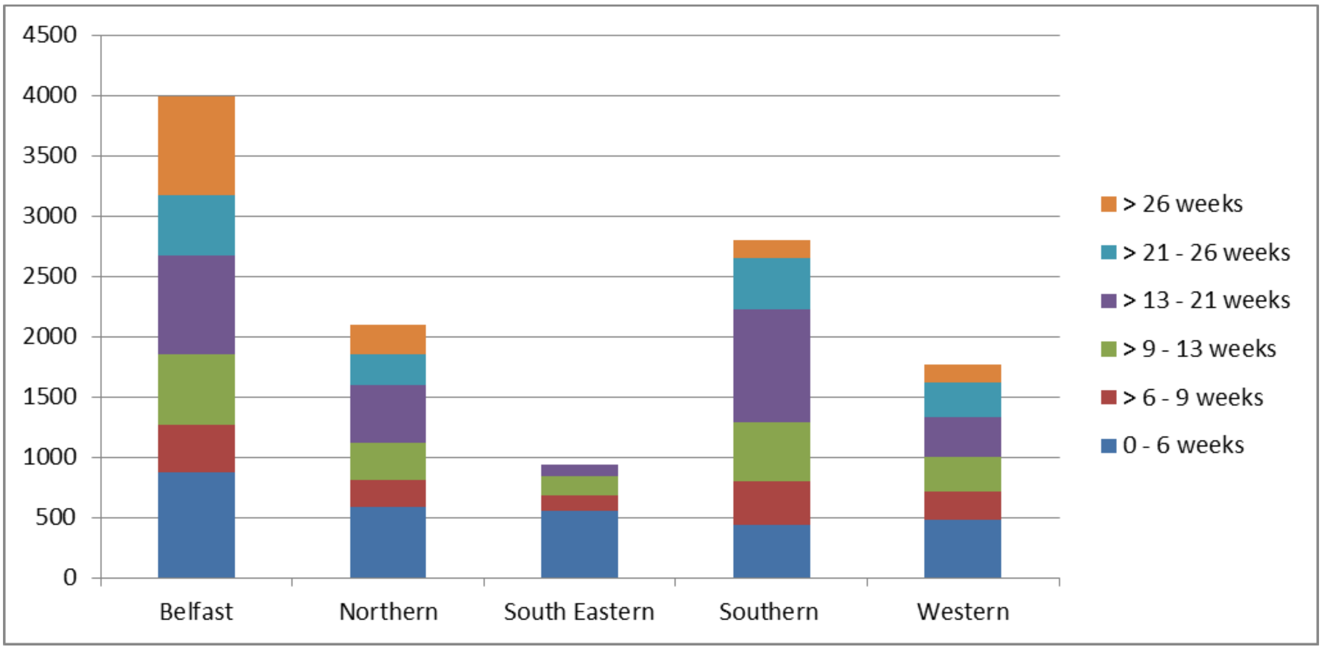


Figure 7.4.9 – Number of Patients Waiting for Echocardiography – Waiting time Breakdown

7.4.4 What is Not Measured

What is not measure but has impact on the patient value and the overall healthcare cost is the financial and health implications of a diagnostic wait. It is not clear in any of the open data or discussed in any of the reports of a method of measuring the impact of a diagnostic wait. The financial cost of a diagnostic wait is important as although the time for a weight is recorded, there is an underlying assumption that limited resources have resulted in a wait and the cost of a wait is neutral. This is not the case as a Diagnostic wait will result in other interventions and management overhead which include;

- Additional GP visits
- Administrative overhead of managing the waiting lists and communicating with the patient and GP.
- Unplanned admission to hospital (selective measurement)
- Additional wide spectrum medication awaiting the full diagnosis
- Lack of patient productivity (perhaps missing work due to illness)
- Patient comparisons of diagnostic tests to build up cases – most tests are single test which are capture at best on PDF.

In addition to the financial cost of the diagnostic wait there is a potential for a cost of health outcomes. As a result of waiting for the diagnostic test and therefore beginning a targeted therapy the issue of condition deterioration, or death, is important and not measured.

7.4.5 Lean Wastes / Lean Non-Value Add Activities

Similar to the previous 2 sections (7.2 and 7.3) this section explores the Lean waste activities in healthcare identified from the literature review in Chapter 3 as a template of Lean wastes in healthcare and explores this application to Diagnostics for Cardiovascular Disease. The diagnostic related wastes below develop the response to the research questions linked to adapting Lean for Long Term Conditions, identifying non-value add activities and identifying where patient value is not delivered.

Table 7.4.5 **– Literature Review Lean Waste Categories Aligned with Cardiovascular Disease: Diagnostic Focus**

Healthcare Failure Area Identified in Chapter 3	***Evidence in Cardiology***
Waiting times	• Waiting is a key waste in diagnostics with large number of patients waiting to complete a test or waiting for the results of the test to be written or communicated. (Emerged in quantitative data and qualitative analysis) • Evidence of growing volumes of waits for key diagnostics over the last 5 years. (Evident in quantitative data) • Performance targets appear to have a link to the waiting times which does not reflect patient value. Performance metrics appear to correlate with demand fluctuation and driving waiting lists. • High volumes of test impact on the turn-around time (TAT)
Medical Complexity	• Impact of delayed decisions is not clear as faster TAT in ED is not evidence of improved patient outcomes. Some studies showing improvement and some showing improved TAT but not outcomes such as reduced length of stay and no overall bed use. (the randomised assessment of treatment using panel assay of cardiac markers –

	(Goldacre, 2011)
Additional Healthcare Visits	• Multiple additional appointments being set up and resources to administer the wait by chasing up test results, healthcare activities to fill gap until full assessment, updating patients, answering progress questions from patients (Emerged in qualitative analysis – Northern Trust Focus group).
Co-ordination of Healthcare resources	• Linkage between effective community based diagnostic testing and hospital admission.
Repeated Procedures	Limited IT systems can result in information on diagnostics completed not being shared which can lead to repeated diagnostic procedures. Use of shared ICT systems such as regional PACS systems (shared diagnostic information) and Electronic Health Record has been reported to reduce repeated procedures as clinician has access to previous test results (Emerged in qualitative analysis – Cardiology Focus group).
Motion/Transport	• Transport to the labs for blood and bodily fluid based tests are a common theme in consideration of diagnostic wastes (Emerged in qualitative analysis – medicines focus group). • Some use of Pneumatic delivery chutes in hospital.
Length of Stay	Presence and absence of effective diagnostics are a key part of the length of stay in a hospital. For example effective diagnostics early may result in patient being discharged or effective early diagnostics may target treatment earlier therefore reducing the length of stay.
Cost	Limited discussion in UK and NI based literature. (Brill, 2013) highlights perverse incentives in USA profit making hospitals to increase the number of diagnostic tests completed which increases cost to the patient/insurer.
Quality	• Test Failure – where the test results in a failed result. Can be picked up by a control line fail process which is built into the test. • Therapies that did not work for the patient (Emerged in

	qualitative analysis – Cardiology focus group). • Value is likely to be most evident in combination of data analytics and diagnostics in a scientific analysis
Emergency Admissions	• Slow or poor diagnostics at emergency can result in waste in the system while effective diagnostics can accelerate the process. • Issue of ED vital signs monitoring not revealing heart attack reflects limitations which may be adjusted with longer term monitoring.
Death	• High radiation risk from many diagnostic tests.
Medication errors	• Test does not identify issue - Heart Attack Issue (Emerged in company discussions) • High false positive can cause excessive demand and false negatives can result in missed conditions and health deterioration.
Infections	• Opportunities to detect Infection – ○ ECG look at heart valves ○ X-ray see if heart enlarged ○ CT/MRI – Has infection spread?
Emerging from this research and not covered in Lean Healthcare Literature	• Multidisciplinary Pathology – Where a lab is doing a number of different test (Batch Processing/Machine exchange which reflects SMED manufacturing issues.) • Batching not covered in healthcare literature but a major theme in LEAN- Evidence in healthcare of batching of tests for collection • Limited understanding of home based monitoring with risk profiling to remove ED appearances - Is there a waste related to prevention? • Emerging technology in vital sign monitoring allowing longer more pervasive monitoring. • Emerging technology to allow quantification within POCD increasingly available • Combination of lateral flow low cost tests with, more

	quantification and digital reading and recording may be advantageous. • Excess or waste demand - stratify the demand 1) remove demand that is without value 2) use point of care tests for diagnostics which don't have as high a quality thresholds 3) address remaining complex demand.

7.4.6 Discussion on the Diagnostics Analysis

In line with the research questions we have considered in this section how a diagnostic for cardiovascular disease can reveal insights for Lean application. The section also considers the waste activities and where patient value is not being met in line with research question 2 and 3. The analysis highlights key areas for considering how Lean can be adapted to long term condition and specifically cardiovascular disease.

In addressing research question 2 about Lean non-value add activities, the analysis of diagnostics revealed that a significant amount of the key Lean non-value add activity or wastes that emerge are linked to the waiting time prior to completing the test and delays receiving the diagnostic results. Some cardiac diagnostic marker studies show improved faster diagnostic turnaround time but the consequence of the improvement don't always lead to reduced length of stay and no overall reduction on the average length of stay (Goodacre et al., 2011). Emergency Departments also have issues with vital signs monitoring not revealing heart attacks which reflects diagnostic limitations which means that emergency department are required to consider a number of approaches with technology to reassure of either a true positive or true negative when assessing if some had a heart attack of just a mild pain. Classic Lean waits were evident with batching of tests to go to labs, transport to the labs and waiting results. Transport, batching and waiting are regarded as key issues in healthcare Lean reforms and have been documented in literature as counter to the principles of flow. The data has also revealed significant waits for patients from cardiology related diagnostics which appear to be getting worse. While there are many unknowns within this there is a potential for Lean tools such as visual management to be used to begin to address this. Additionally the data reveals some issues of performance being driven by other measures than patient value which needs exposed and addressed. Opportunities also emerge in utilising technology identify and share best practice across HSC trusts.

7.5 Hospital Based Care

The previous section of the thesis analysed diagnostics use for cardiovascular disease patients in the care pathway. This contributed to the aim of the thesis by analysing the role of Lean thinking application to integrated healthcare patient pathways. In figure 7.2.1 and duplicated in figure 7.5.1 below one can see hospital based care is the next set of activities within the patient value chain. The hospital based interventions have a series of activities and outcomes which are a key element related to the patient pathway.

It should be noted that although there is a logical flow from the GP through to diagnostics and to the Hospital this is not a complete picture of the complexity of patients. Patients may enter hospital care via an ambulance or emergency department as unplanned visitor as the result of a sudden heart attack of cardiac related episode. Equally the hospital may review the patient at a hospital outpatient clinic and send the patient to get diagnostic tests prior to a decision about admitting the patient for surgery or discharging them without inpatient treatment. The analysis of hospital based care in this section will include quantitative and qualitative analysis with some consideration of these additional sources of patients. To continue addressing the research question of how Lean can be adapted for long term conditions this section will review hospital based care activities and identifying Lean wastes within this. It will continue to use cardiovascular disease as an example of a long term conditions to provide focus and application.

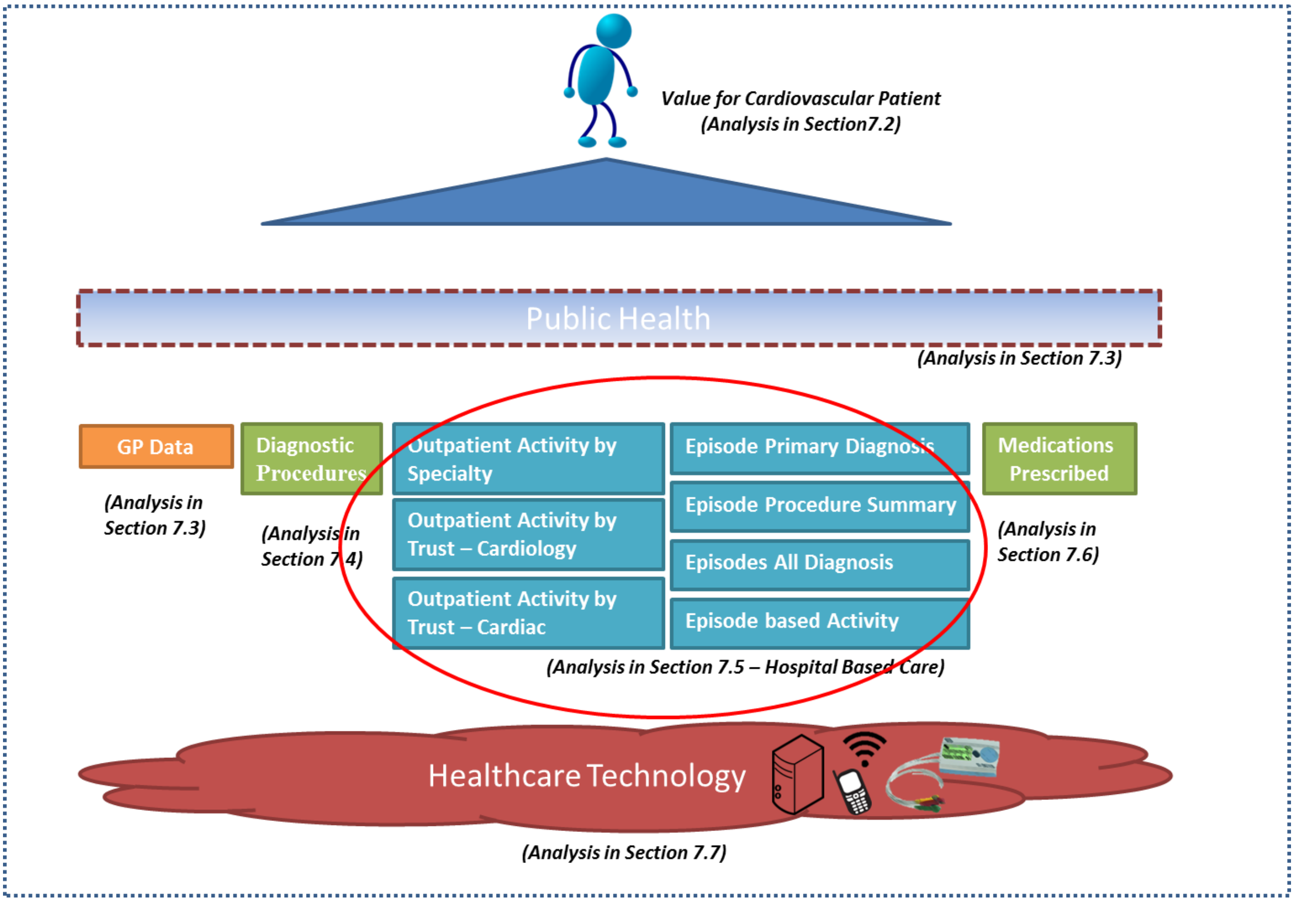


Figure 7.5.1 – Cardiovascular Disease Data Set – Focus on Hospital Based Care

7.5.1.1 Hospital Based Care Definitions

Hospital based care is divided into outpatient and inpatients status. These definitions of the types of patients in the NHS website refers to "If you've been referred to hospital but don't need to stay overnight, it means you're being treated as an outpatient or a day case". In the case of an inpatient they have the following description "If you've been referred to hospital for an operation or test and you need to stay overnight, it means you're being treated as an inpatient" (NHS Choices, 2018).

Outpatient activity will be undertaken to assess the patient based on a clinical concern raised and referred by a GP. The outpatient clinic will be provided by a specialist and managed by a consultant for a speciality such as cardiology. The consultant led clinic will make an assessment of the presenting symptom and make a decision in consultation with the patient on the next steps on the clinical pathway. This could include advice to a patient or GP, referral to a diagnostic procedure, referral to inpatient procedures or review over a period of time. The outpatient clinic will also manage the review appointments post inpatient activities to review progress or recovery where necessary. The qualitative analysis revealed that in the case of heart failure, nurses were employed to monitor patients post discharge from hospital.

Further categorisation of patients beyond inpatient and outpatient is recognised based on the admission type to hospital. Planned and unplanned (or unscheduled) admissions are key drivers impacting the patient and the care pathway. The NHS is a budget constrained organisation and Porter (2016, Pg. 90) notes that “fixed budgets inevitably lead to long waits for nonemergency care and create pressure to increase budgets each year”. The final definition of note is the Average Length of Stay (ALOS) which is a critical measure across the majority of hospitals globally. Specific specialities will have different standards with heart failure being a condition with a longer expected ALOS. Omar HR (2017) highlights discussion on the reasons for longer

The length of stay for acute heart failure is a constant theme for literature as there is a link between a long stay and poor health outcomes however it is unclear if this is correlation or causation (Omar and Guglin, 2017). The purpose of the thesis is not to advance the knowledge of medicine but these types of admissions and patient status provide considerations for the research questions of the thesis. They reflect operational design and commissioning decisions with an impact on value and waste which are at the core of Lean reform.

7.5.1.2 The Role of Hospital Based Care

The role of hospital based care is to provide specialist assessment, intervention and monitoring. While the general practitioner is concerned with healthcare for the patient, the hospital is divided into specialist areas with supporting diagnostic activities. The hospital based care is particularly relevant to this thesis as many patients with cardiovascular disease attend hospital for assessment, interventions and in many cases readmission to hospital. Acute exacerbations of their condition such as through chest pain or heart attack will often result in a visit to hospital based care. Heart failure, which reflects the declining function of the heart, for example is the most common cause of hospitalisation in people aged over 65 years (Mendoza et al., 2009). Heart failure patients in this study of Spanish patients had a readmission rate of 45% with on average 2 readmissions per patient.

Cardiovascular disease activity in a hospital will focus on circulatory system but can require interventions which are not within the cardiovascular disease specialism. Examples of cardiovascular disease interventions include; angioplastry, transplantation, bypass, implants, coronary artery, bypass graft, and lipid modification (Yock et al., 2015). The role of the hospital may also extend beyond surgical interventions as clinicians will have outpatient activities which follow the patient to the home for a period after clinical intervention in the hospital. The key purpose is to improve the outcomes for the patient and prevent readmissions.

The role of the hospital as part of the aims of the thesis will be discussed through this sections with the use of quantitative and qualitative analysis for cardiovascular disease patients.

7.5.1.3 Hospital Based Care Future Development

To understand the hospital based care implication on the research one must also reflect on the emerging configurations of services and the hospital based care of the future. Hospital at Home, remote monitoring services and self-management are some of the emerging as areas of interest in the hospital based future developments (Mendoza et al., 2009). Emerging technology, market developments and research studies are influencing decisions in these areas to change care models. Some technologies are emerging to create opportunities for potential new models which then undergo research scrutiny to take into account the clinical, operational and economic justification for the new models. Understanding future hospital based care models is particularly important for the thesis research question 3 when asking "Can health technology from data focused technology assist in redefining patient value". This will be reflected upon in the analysis and discussion of this section.

7.5.1.4 Hospital Based Care in This Thesis

With the definition, role and future direction explained, the remainder of section 7.5 will reflect the common approach of use in the previous sections of 7.2, 7.3 and 7.4 by analysing;

- Current hospital based care interventions in academic and grey papers
- Current measures and data within the Northern Ireland healthcare system
- What is not measured
- Hospital based care activities against the Lean non-value add activities identified in academic literature in Chapters 1-7.

From this analysis we can then contribute to answering the research questions of how Lean can be adapted for Long Term Conditions (Research Question 1) and contribute to identifying methods for Health Technology to address Lean Non-Value Add Activities

(Research Question 2). The analysis will also build some insight into addressing where health technology can assist in redefining patient value which reflects research question 3. Open data available is the most exhaustive in hospital based care as the standards and consistency across the hospitals is much more mature than other areas of health provision covered in this thesis. This may reflect efforts to compare and contrast performance across the hospitals in the region, UK and globally.

7.5.2 Analysis of Hospital Based Care in Academic Papers and Grey Materials

As research question one focuses on understanding the Lean waste activities it is important to continue to investigate the value stream map of cardiovascular disease and specifically activities related to hospital based care. These activities will indicate the drivers that create value or waste to a cardiovascular patient. Academic papers and grey papers such as work instructions and best practice guidance provide significant insight on the activities and challenges that are known in the current working practice. Hospital based care is the most rich for this type of material as it reflects more similar activities across providers than in public health or community care. Insight from these has been discussed through the qualitative analysis to gain insight on what is best practice and what is actual practice. To address the research questions the hospital based care will require analysis for Lean related issues and cardiovascular patient outcomes. The key points when analysing diagnostics are;

- Emergency care
- Emerging role of Specialist Centres
- Reducing readmissions
- Emerging hospital models and condition Management

The strategic direction of many health policies is to reduce the dependence on care in a hospital. This reflects various healthy ageing strategies such as mentioned in the Innovate UK Life Sciences Industrial Strategy (Office for Life Sciences, 2017, Pg. 17) where they state;

> “ As we move to a setting where almost 30% of the population will be over the age of 65, a wide range of engineering, digital monitoring and technology based solutions will be required to maintain mobility, allow people to stay at home and provide much more effective out of hospital care.”

While it is accepted that the future progresses towards at home services, there remains a need for hospital based care as part of the delivery of care.

7.5.2.1 Emergency Care

Emergency departments are under extreme pressure and scrutiny. Target such as a maximum four hour wait for 95% of patients are monitored for all hospitals as part of the core standards set out in the NHS constitution (The Kings Fund, 2017). Despite the target, most organisations continue to fall below the 95% threshold and preparations for peak demands such as increasing staff and increased additional resources have had little impact on addressing the issues (The Kings Fund, 2017). Demand prevention is a significant topic for understanding value from a patient perspective and the purpose of this thesis. Value can't be represented as a 4 hour wait from a patient perspective as the reason for them needing to go to an ED is not understood (Gubb, 2009). Emergency care issues are linked to the whole system with decisions to admit a patient to the hospital linking to the number of beds available which is directly related to the ability to discharge patients. Having a backlog of discharge patients will therefore lead to long waits in ED to be admitted. Elderly, vulnerable people and complex needs patients in particular often require a multi-sector and multi-agency approach as social care assessments are made to ensure that adequate support is available when discharged to the community.

7.5.2.2 Emerging role of specialist centres

There is a significant role for consolidated specialised cardiology expertise where the most complex procedures can be completed in the safest manner possible. The NHS Five year's forward review makes a statement (NHS 2014) about new care models. Specifically highlighting that greater standardisation can occur when services are consolidated. The concept of standardisation of best practice is a key Lean theme and if associated with continuous improvement would largely be regarded as positive.

As evidence of improvement within the consolidation, they highlight a 17% reduction in 30 day mortality where 32 stroke services were reduced to 8 specialist units. Other studies highlighted improvements such as mortality rates, post-operative complications and patient length of stay. The safety of procedures is often linked to the volume of similar procedures completed by a surgeon or clinician and this cannot be done with community based practitioners where the volumes of a specific procedure will be significantly lower.

The concept of standardising is supported in many Lean applications and would be a common improvement strategy. Similarly sharing best practices is a key Lean approach and is advanced by best practice guidance. The organisation responsible for best practice guidance or standards is the National Institute for Health and Care Excellence (NICE, 2017). The NICE guidance is an attempt to implement best practice within the NHS as an approach of standardising the best known methods.

For cardiovascular disease the NICE clinical guidance had 58 separate documents with many of them being frequently updated and some addressing similar or overlapping areas. For example “Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease (CG172)” was created in Nov 2013. In Sept 2017 the website reports that the document is under review and likely to be updated with further emerging evidence around the use of beta-blocker treatments. This highlights the constant nature of update and change within the profession to maintain current best practice. The guidance also has a number of politically sensitive statements attached which releases the clinician from following the guidance as mandatory as they must take ownership of clinical decisions. Secondly the advice encourages clinical commissioners to use the advice without mandating this. The guidance is couched in language about needing to reflect local and national priorities as part of considering implementation of the advice. This softer language allows for local budget constraints. Similarly in the area of myocardial infarction there is further guidance available for "Myocardial infarction with ST-segment elevation: acute management (CG167)". This therefore means that clinicians, even in a very specific area, must be aware of a series of guidance, standards and pathway related instructions which they must interpret for the needs of the patient and within the constraints of the local commissioner and hospital. NICE defined conditions and pathways related to cardiovascular conditions include pathways, protocols and guidance for preventing treating and supporting providers delivering care. NICE Pathways include;

- Cardiovascular disease prevention
- Identification of risk
- Lifestyle changes for prevention of cardiovascular disease (diet, physical activity, weight management, smoking)
- Lipid modification therapy

The use of operational procedure in healthcare are however more complex and difficult than operational procedure in the Toyota Production Lines. Volume wise there are significant issues as in England there are more than 168 acute hospital trusts with a significant number of these trust having more than one hospital. In Northern Ireland there are 5 Health and social care trusts with all of the trusts having more than 1 hospital and Belfast having 5 hospitals (excluding mental health facilities). The logistics of managing and policing guidance would be a mammoth task. Secondly there is variance of presenting patient with racial genetics, diets, sex and many other factors having a significant impact both on the conditions and the ability to respond to interventions or therapy. This requires the guidance to revert to the clinician as the key owner of treatment under medical opinion. Thirdly, medicine is a changing landscape with advances in medicine, changes in medication, evolving patient characteristics. This means that what was previous best practice will be superseded, the medication will have been replaced and the patient may be living 10 years longer than before with more complex conditions. This leads to a need to constantly question guidance against the latest finding which can undermine confidence and adherence to guidance.

All of which have an impact on key operational issues. The challenges of the guidance and operation practice are;

1. Keep up to date with the multitude of NICE guidance work instructions.
2. Balancing the commissioning needs and priorities for your area against the guidance.
3. In addition a hospital or specialist centre may be addressing the needs of a numbers of commissioners due to overlapping boundaries and each may have slightly different needs.

There is however mitigation against the risk of all clinicians ignoring the guidance which is the potential to be deemed to be clinically negligent and secondly the influence of peer influence. The NICE guidance documents have a substantial backing within the clinical community as they have been created by their peers. On the negative of this a clinician who wilfully goes against the guidance and ends up in a negligence case will be the subject of scrutiny and on the defensive against their clinical behaviours.

In summarising the key areas of relevance for this thesis in the emerging role of specialist centres one can find the following areas being of relevance

- The role of the specialist is being developed which supports Lean and transformation which could reduce errors and improve quality

- Guidance and work instructions are developed and being used which reflects at a high level the need to seek best practice and improve from there
- Guidance and standards are discretionary and subject to clinical adjustment and local priorities.
- Large volumes of updated guidance material may make the system unworkable without technical assistance or decision support.

7.5.2.3 Readmissions and Condition Management

Hospital readmissions, which are an unplanned admission to hospital following an inpatient episode1, attract a significant amount of attention both in literature and operational focus. The USA centre for Medicare and Medicaid services data, reports that two of the three highest volumes of readmissions are from cardiovascular related patients (Berenson et al., 2012). Heart Failure, Acute Myocardial Infarction (Heart Attack) and Pneumonia are the three conditions with the highest readmissions within 30 days and jointly make up 12% of all hospital admissions. The NHS also recognises readmissions as a serious financial and health outcome challenge and readmissions reflect Lean principles of failure leading to rework.

Prevention is a key focus for hospitals; however there are many documented reasons why a patient will readmit with many of these being linked to either patient behaviour (Greene, 2012). The resolutions are not simple and some interventions have led to increasing readmissions as access to the clinicians had increased (Joynt and Jha, 2012). The challenge is made more complex by the nature of the types of patients this impacts as this is some of the sickest patients being kept alive. There is a need to risk adjust the measures to understand poor quality service versus sick patients (Berenson et al., 2012). Measures and understanding of which readmissions could be avoided vary heavily between clinical opinion and managerial data (Joynt and Jha, 2012). Related to previous discussions in this thesis about the connection along the value stream, studies have highlighted that many factors are beyond the hospitals control and within the community (Joynt and Jha, 2012). Additionally communities with higher levels of deprivation will have higher levels of readmissions reflecting a need to personalise discharge approaches (Berenson et al., 2012).A significant number of studies have broken down large amounts of data over tens of thousands of patients to attempt to understand cardiovascular patients with a focus on heart failure profiles and potential reason for readmissions which are reflected in table 7.5.1.

Table 7.5.1 – Hospital Readmission Reasons Literature for Cardiology

Potential Factors Impacting Readmissions Rates	Description	Data	Publication
Use of Electronic Health Record (EHR)	Study explores if electronic health record in hospital reduces readmissions due to better sharing of data.	Readmission Rate = Full EHR-30% Partial EHR 29% No EHR 32%	Patterson et al., 2014 Berenson et al., 2012
Ethnicity	Ethnicity has linkage to responses to various therapies and drugs. Some studies even highlighting differences on blood pressure responses.	85% white,	Patterson et al., 2014
Age	Age has a direct correlation to heart Failure.	Average age 81,	Patterson et al., 2014
Comorbidity	Having a number of health conditions is highly likely in a significant number of patients.	59% Comorbidity	Patterson et al., 2014 & Greene, 2012
Medicines	Issues associated to prescribing the	61% Ace	Patterson et

Reconciliation	right medicine and this being available to the patient. Known issues such as wrong medication being prescribed due to conflict with other conditions such as asthma or diabetes.	inhibitors or beta blockers.	al., 2014 Greene, 2012 Berenson et al., 2012
Medicine Compliance	Medicines compliance relates to the patient taking the medicines as prescribed. Patients may not take medication due to forgetfulness, toxic side effects of medication, distrust of the medicine or belief that they don't need it.	In some studies up to 51% of medications are not taken as prescribed (not specifically related to Cardiovascular disease).	Patterson et al., 2014
Deprivation	Demographics, deprivation, education and social status have impact on readmission levels.	Poor and minority factors result in higher readmission	Patterson et al., 2014 Greene, 2012
Contact with Your Community Doctor	Post discharge contact with a primary care (GP) quickly after being discharged will have a significant impact on the levels of readmission.	Post discharge contact doctor within 1 week.	Greene, 2012
Length of Stay	Longer lengths of stay have a relationship to the likelihood of readmission. Shorter stays being a proxy for less complication therefore a longer stay may reflect complication and potential comorbidity.		Greene, 2012

Defect free discharge	This reflects the discharge team following protocols at the time of discharge.	51% readmission	Patterson et al., 2010
ED visits in the last 6 months.	The number of emergency room visits in last 6 months has a direct relationship to the likelihood of readmission.		Greene, 2012
Discharge and Post Discharge Risks	Hospital acquired infections while not specifically related to the cardiovascular work can result in a reason for readmission. Premature discharge has been identified as a reason for some readmissions. This can be related to pressure on beds and reducing average length of stay in hospital. Indicators of upcoming readmissions include fluid build-up in lungs, tiredness, weakness, light head, short breath, chest pain and racing heart.		Berenson et al., 2012

In analysing the literature covering readmissions in cardiovascular disease one can break all the factors impacting the likelihood of readmissions into two broad categories of care provision factors and patient factors as shown in figure 7.5.1. This is relevant to the thesis as within these reasons for failure are potential opportunities for healthcare technology to identify the issue or address the issue to improve patient value.

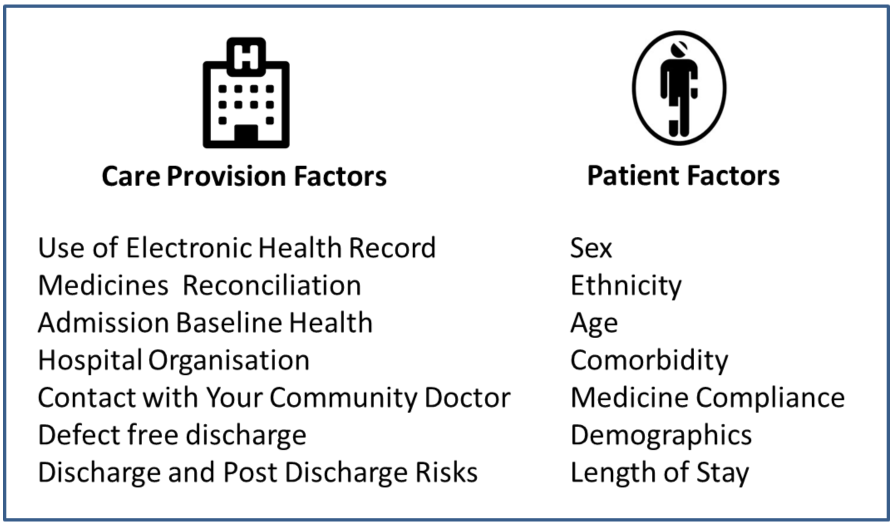


Figure 7.5.2 – Summarising the Readmission Risk Factors for Readmission

In summarising the area of readmissions it is clear that re-admissions are a Lean waste for both provider costs and patient health outcomes. The patient factors reflect a risk element which will be personal to the factors of birth, behaviour and lifestyle. From these a personalised prediction can be made about the likelihood of readmission and compliance. This is not typical Lean reform approach as risk profiling of the individual is not a common response although there is some use of risk metrics based on symptoms. The closest that could be found in Lean literature would be around maintenance of machinery or similar. From the risk profiling new activities may be drawn to address the patient value. Technology may have options of simplifying and supporting decisions through risk profiling and personalisation.

Provider waste is also evident in areas such as clear discharge instructions, assessing specific functions of the heart prior to discharge; ensuring prescriptions are available, addressing smoking cessation and issuing beta blockers where Left Ventricle Systolic Dysfunction is present. There does however need to be more research to prove the effectiveness of these interventions. There is evidence that these are not adhered to but there is less evidence that adherence results in better outcomes. This is highlighted in the following quote from Paterson;

> "Only conformity with a measure for prescription of a beta blocker for left ventricular systolic dysfunction was significantly associated with a lower risk of 60 day to 90 day mortality...." (Patterson et al., 2010, Pg. 6)

It still stands to reason however that best practice is implemented, measured and improved through a continuous improvement cycle. Finally, the area of linkage between the hospital and the community is evident as an area that is resulting in patient value not being achieved. This supports the Lean literature gaps that Lean healthcare needs to address patient value across the care provision silos.

7.5.2.4 Emerging Hospital Models and Condition Management

Care providers have sought to innovate by seeking to establish home based and community care programmes that align with hospital programmes and attempt to either provide a step down service from hospital or complement hospital programmes to avoid admission or readmission. Some are referred to as “hospital at home” to reflect more complex care provision in a home setting with Heart Failure clinics being a significant home based care programmes (Mendoza et al., 2009). Studies of the effectiveness of the home based care are limited. They are difficult to compare due to changing inclusion criteria for patients and don’t provide a complete view of the costs and outcomes. The trials and studies are highlighted in Table 7.5.2.

Table 7.5.2 – Emerging Cardiology Healthcare Alternative Models

Author	Location	Notes
Patel et al., 2008	Sweden	Home based care provided until the patient was improving. Some exclusion of specific types of patients. Specific parameters around weight, swelling and clinical health identified to mark the end of the service. Telephone escalation available after the service had ended.
Mendoza et al., 2009	Spain	Targeted at early diagnosed Heart Failure. Use of New York Heart Association classifications of patients to agree criteria for patients who could participate. Narrower scope of patients than Swedish work.
Tibaldi et al., 2009	Italy	Targeted at narrow scope of patients with Heart Failure. Use of New York Heart Association classifications. Some additional criteria around previous diagnostic investigations.

The studies focus on three core areas of costs, health outcomes and patient related quality. In terms of the costs the studies showed saving in the early phases in general and comparable costs in the longer term. Health outcomes had no real impact on the number of readmissions however there was some improvement in the time to first readmission (longer). The patient quality aspect however was much more positive as health linked quality of life was measured. The studies have known limitation in that there are not significant number of trials that have been reviewed with academic rigour despite the hospital at home service being developed across many hospital trusts. The comparisons often struggle to operate clinical trials as comparison to control groups can be somewhat difficult. The above trials have patient groups of less than 100 patients therefore the volumes and are not significant in overall health terms and withdrawal from the research and deaths can impact the studies significantly. The studies however are relevant to this thesis in three specific areas. Firstly they expand their measurements to quality of life for patients with reference to Barthel index measurements which are highly relevant to the Lean concept of value defined by a patient. The measure is not limited to the completion of the clinical intervention but the impact on the patient. Secondly, the measurements looks at longer term measurements such as 1 year after surgery which allows a more holistic view beyond a specific treatment both for the outcome of the surgery from a clinical perspective but also from the patients view. This outcome measure is more closely aligned to a Lean value perspective and is often absent from feedback to continuous improvement initiatives and Lean as seen in most healthcare literature. In summary, these concepts of extended measures and patient quality of life measures feeding into continuous improvement are very relevant when looking at cardiovascular disease and how Lean can be used in long term conditions. In addition technology has options to address the barriers to capturing the data to support new models in ways not explored in the RCT’s.

7.5.3 Analysis of Current Measures and Data within the System

This section analysis quantitative data focused on hospital based care. The majority of hospital based care related to cardiovascular disease in Northern Ireland is found within the health and social care trusts. Some activity is completed in the private sector but this is of a significantly smaller scale therefore has been determined as out of scope.

Quantitative data is available through a number of open data sources with the main challenge being to identify and navigate to the relevant information. The selection of data used for analysis can present a number of challenges as different sources of data will group and present data in different ways depending on the collection purpose. For example the Northern Ireland Statistics and Research Agency (NISRA, 2017) has a large amount of data which is grouped in various categories. Utilising a grouping based on a local government boundary, for example, will remove the ability to understand a hospitals performance due to hospital patients crossing local government boundaries. NISRA statistics may additionally focus on consistent measures for year on year comparisons but subtle changes in year on year healthcare relevance, which the health trusts will capture, will be missed. The healthcare trusts however may change a measure from one year to the next and the ability to compare year on year is lost. In summary, each of the big data sets must be understood for content and context.

To access the relevant data on cardiology one must navigate through a multitude of information on other clinical specialisms which reflect the overall hospital performance. For example “New to Review Comparisons”, required navigation through over 650 pages of other data. This is highlighted to emphasise that although data may reveal clinical and operational insights this is not easily accessible even if the clinicians knew where to look and the exact meaning of the data. This point emerged in qualitative focus groups where the participants were very interested in the breadth of the data and wanted to know how to navigate and get this. Similarly when working with cardiologist during the early part of the thesis a small sampling of data required the input from the cardiologist, hospital ICT specialists and waiting list specialists as the multitude of joining systems, with internal names and codes were not understood by even the clinician operating on the patient and the subtleties of clinical codes were not understood by ICT staff or administrators.

The core data which is analysed and presented in this section relates to open source data from within the 5 Health and Social Care Trusts. The data has been processed to draw out further information. To present this, the thesis will cover;

- Outpatient Waiting Times
- New to Review Comparisons
- Cancelations
- Inpatient Waiting Times
- Cardiovascular Disease in the Context of Hospital Activity
- Demographics of Cardiology Patients
- Bed Utilisation for Cardiovascular Patients
- Comparisons across hospital trusts

Table 7.5.3 is provided to highlight that the data is not provided in an easy to use format but must be separated from other data, reprocessed from potentially other formats (such as PDF or CSV) and analytical processes are used to join, calculate and present information.

Table 7.5.3 – Hospital Source Data

Specific Criteria Extracted	Type of Data	Processing	Links
34: Specialty 320	Extracted From CSV	Trust Summary Figures Extracted	https://www.health-ni.gov.uk/publications/hospital-statistics-outpatient-activity-statistics-201617
34: Specialty 320	Extracted From PDF	Trus0074 Summary Figures Extracted	https://www.health-ni.gov.uk/sites/default/files/publications/health/hs-outpatient-stats-15-16.pdf
NISRA Data	Downloaded	Further processing to analyse data and make complete picture.	http://www.ninis2.nisra.gov.uk/public/PivotGrid.aspx?ds=6530&lh=37&yn=2007-2014&sk=134&sn=Health+and+Social+Care&yearfilter=

7.5.3.1 Outpatient Waiting Times

Waiting is a classic waste in Lean (Bicheno and Holweg, 2016). In healthcare waiting has an immediate impact on the utilisation of healthcare resources for no value and reduced value for health outcomes therefore having both a financial and health disadvantage. To analyse the outpatient waiting time processing of the data was completed to convert the waiting categories and patient counts to a total number of days waiting. This is not typically done as comparisons across years are note completed and the categorisation into groupings, such as 12-15 weeks is more common. This however lacks the year on year performance comparison of total waiting time. The data has been processed to address some of the changing categories over the 5 years and the figures have use proxy data based on mid-point of a time category to allow a fuller number. For example where 10 patients were waiting 12-15 weeks then a mid-point of 13.5 weeks was used to multiply by the number of days and number of patients waiting that duration. While this has some limitations due to the nature of the reported data, this does however paint an interesting picture which is show in the figure below.

By using this data it was possible to calculate that in the last reporting quarter **1.6 million** (1601454) days are used in Northern Ireland waiting for an outpatient appointment across the 5 HSC trusts. Calculations across the time periods are not possible as the figures do not provide unique patient identifiers so there is no way to identify where a patient may have appeared on the waiting list across a number of time periods.

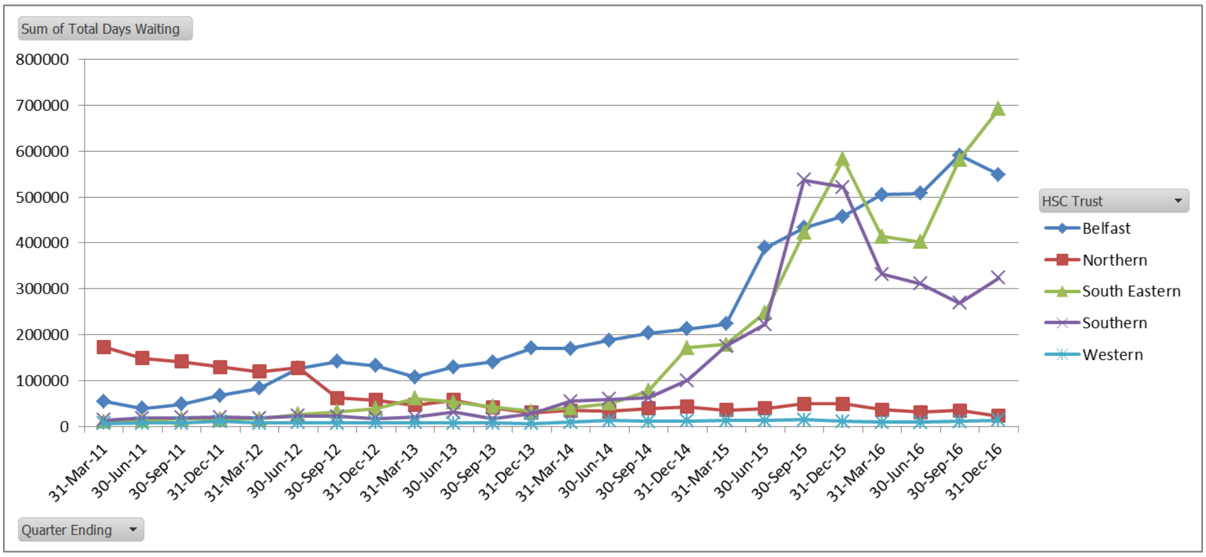


Figure 7.5.3 - Days waiting for Cardiology Outpatient Appointment 2011-2016 (Source data: Department of Health, 2017, Outpatient Activity)

If this figure is then calculated for the individual patient there is an average of **109 days waiting** across the 5 trusts in the final measurement. To cross correlate this with other figures and analysis was done of the mid-point of waiting list. In Belfast in the final measurement the mid-point would be the 1921st patient. This patient was found to be waiting in the category 18-26 weeks or in day terms 126-182 days therefore taking into account the variance across the trust the 109 days figure appears to largely in line with the other figure and possibly a little conservative.

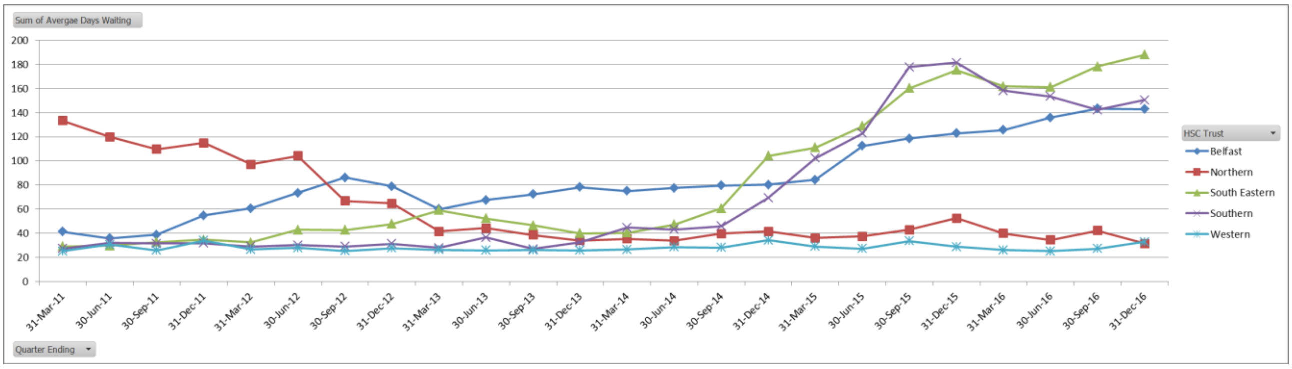


Figure 7.5.4 Average Number of days waits for Cardiology 2011-2016 (Source data: Department of Health, 2017, Outpatient Activity)

The longitudinal trend is also alarming as this appears to be increasing significantly in particularly for the high volume trusts. The trends however do not reflect a continually decline in performance but shifts and changes within the 5 years which would require further analysis and highlight a need for continuous improvement which utilises data.

7.5.3.2 New to Review Appointments

When analysing the data for outpatient activity there are a number of factors which can be useful in understanding how a service is being delivered and the types of appointments being performed is one of these. Health and social care trust figures report data that can be used to identify variance in approaches and Lean and six sigma approaches utilise variance as a tool to identify where there is potential for waste or improvement. Comparisons will need some level of context as this is not comparing the performance of two machines in a factory and patient cohorts or user needs may require some variance but there is still a key assumption that variance and waste will be linked as the best practice has not been identified and translated to be standard practice.

Figure 7.5.5 for the new cardiology outpatients compares the volume of new appointments over the period 2011- 2016 and utilise comparisons across the trusts. Over the 5 year period there is evidence of some growth in the number of outpatient appointments with the Belfast Trust having the largest number of appointments. As Belfast is the largest trust based in the largest city in Northern Ireland this in itself is not surprising. The diagram below highlights that Belfast trust is completing the largest number of outpatient activities with approximately 44% of the activities and over 4 times the volume of the smallest provider which is the South Eastern Trust. Not easily detected in the graphs however is the growth in the number of new appointments during this time period. In 2011 there was 17,954 new appointments compared to 23,188 in 2015-16 which reflects as 29% growth in the number of new appointments. This is relevant for Lean as it reflects an understanding of expanding capacity to address demand. This however does not appear to be keeping pace with either the diagnostics waits or the outpatient appointment waits. This leaves questions about a system designed not to cope with the demand. In addition the qualitative analysis revealed some questions about the quality of the referrals with a belief that the volumes were growing due to inexperience of the referrer.

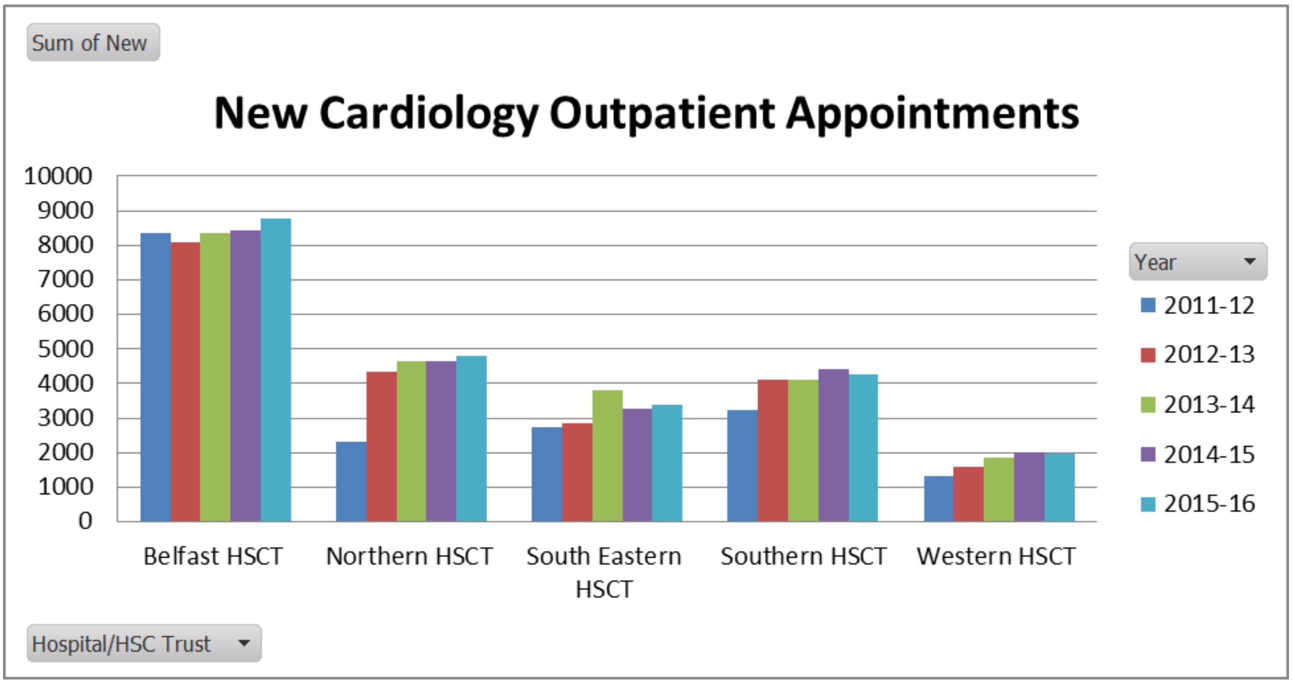


Figure 7.5.5 – New Cardiology Outpatient Appointments (Source data: Department of Health, 2017, Outpatient Activity)

Unlike the growth in the number of new appointments, the number of review appointments has fallen by 2454 from 35,490 to 33,036 which represent 6.9% decline in the number of review appointments. This means that in total there is a net gain of 2780 appointments being available over the 5 years. What is not clear in the data however is the impact of the less review appointments being made available? This is particularly relevant as the focus of the thesis is in the growth of long term conditions. Long term conditions are by definition not healed and therefore will require continuous input from clinicians over time. There is potential that this input is being completed by the GP. From a Lean perspective there is a potential of more value add activities being reduced although this can't be quantified by the available data.

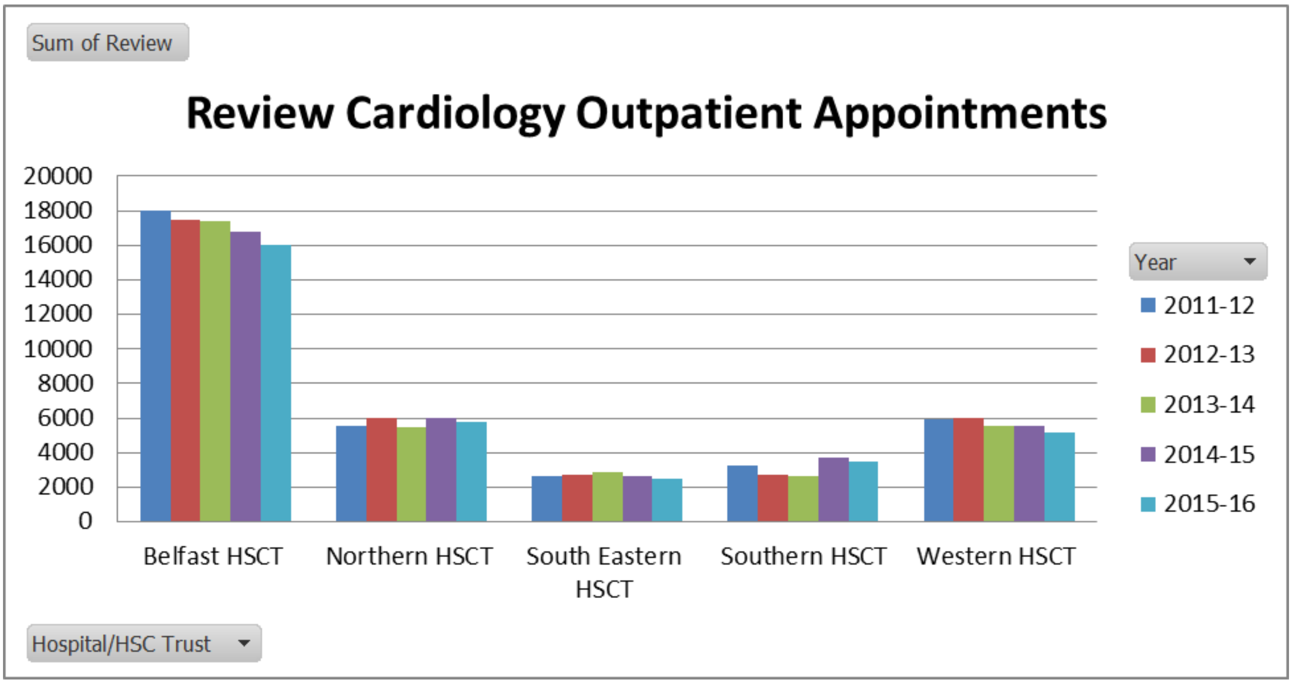


Figure 7.5.6 – Review Cardiology Outpatient Appointments (Source data: Department of Health, 2017, Outpatient Activity)

Further analysis of the number of review appointments reveals that a reduction in the total number of review appointments is not universal. Three out of five of the trusts have actually increased the number of review appointments. This detail therefore highlights that the total number is masking variance within the trusts the Belfast trust being the only trust to maintain a falling number over the 5 years. This is highlighted in the Table 7.5.5 where one can see falling numbers in Belfast with fluctuating appointments in other trusts.

Table 7.5.4 – Number of Cardiology Review Appointments **(Source data: Department of Health, 2017, Outpatient Activity)**

Row Labels	**Belfast HSCT**	**Northern HSCT**	**South Eastern HSCT**	**Southern HSCT**	**Western HSCT**
2011-12	18029	5581	2663	3274	5943
2012-13	17469	6004	2723	2734	6012
2013-14	17392	5471	2886	2617	5547
2014-15	16780	6022	2675	3701	5543
2015-16	16026	5804	2504	3502	5200

Explorations of new-to-review ratios are also of interest in the analysis of variance. Theoretically a group of patients being treated under a similar care pathway would have a similar level of review appointments. Over a 5 year period one would also expect the ratio to stay reasonably static as patients would be discharged at similar points. This comparison is not a standard measure that would be completed within any of the open data information and therefore actions or investigations are unlikely to have been completed to understand this variance. In the chart below the % of appointments which are reviews is provided and compared across the 5 years and across the trusts.

Across the five trusts one can see that there is substantial variance in the ratios with a difference of approximately 29%. When looking at one year we find that a Minimum 43 and maximum 72 and similar cases during the time period. The Western Trust and the South Eastern are the outliers at 42 and 72. It is possible that when looking at these Trusts, the services have been configured in ways which explain and justify the difference however there is still a question of identifying best practice for patient value, outcomes and costs. In the case of readmissions (patients being readmitted after being discharged) which is known as key waste area this level of variance is likely to reveal opportunities for best practice that has reduced readmissions or has evidence of larger number of readmissions. Lean is focused on scientific management and this reflects opportunity to improve which has not been realised.

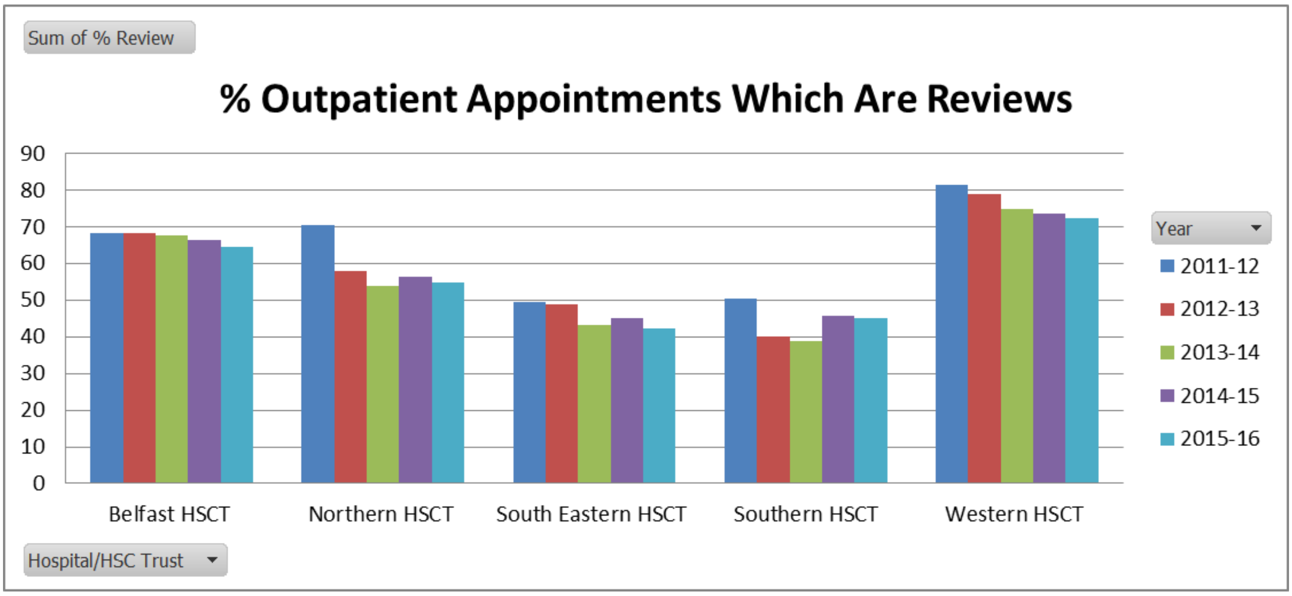


Figure 7.5.7 –Outpatient Appointments as a Percentage of the Total Appointments (Source data: Department of Health, 2017, Outpatient Activity)

7.5.3.3 Cancelations

The previous figures have all looked at appointments that have successful taken place but the open data also gives us access to appointments that have not taken place. These fall into three categories of DNA, CNA and Cancelations. The term DNA in healthcare is a standard healthcare term meaning “Did Not Attend”. This means a scheduled appointment has been missed by the patient without any apology or attempt to cancel or move the appointment. The term CNA means Can Not Attend and reflects a cancelled appointment where notification has taken place. In the cases of a CNA, an attempt may have been made to fill the appointment with another patient therefore there is a lower likelihood of waste but additional resource will be used attempting to fill vacant slots. Cancellations are the third category and in this case this will be a failed appointment due to the healthcare organisation rather than the patient.

From a Lean perspective, cancelations across the HSC trusts are all non-value add within the system as the patient has not received the care that was needed. This issue is not a new issue attempts have been made of the last couple of decades to reduce this number through various initiatives. Despite the issue being highlighted and written about over the last 25 years it remains a constant issue with the evidence being highlighted below in the last 5 years figures.

The figures for DNA’s, shown in figure 7.5.8, as a % of attendances provides a mechanisms of putting a scale to the issue in relation to the number of successful appointments. Belfast clearly stands as an outlier although improvements appear to be evident. Similarly the Northern Trust appears to have made the most progress in improvement to the lowest level of DNA’s. Although it is useful as a context to make benchmark comparisons one needs to be mindful that a benchmark of failure is not a Lean approach as Value is not being delivered through event the best performing trusts.

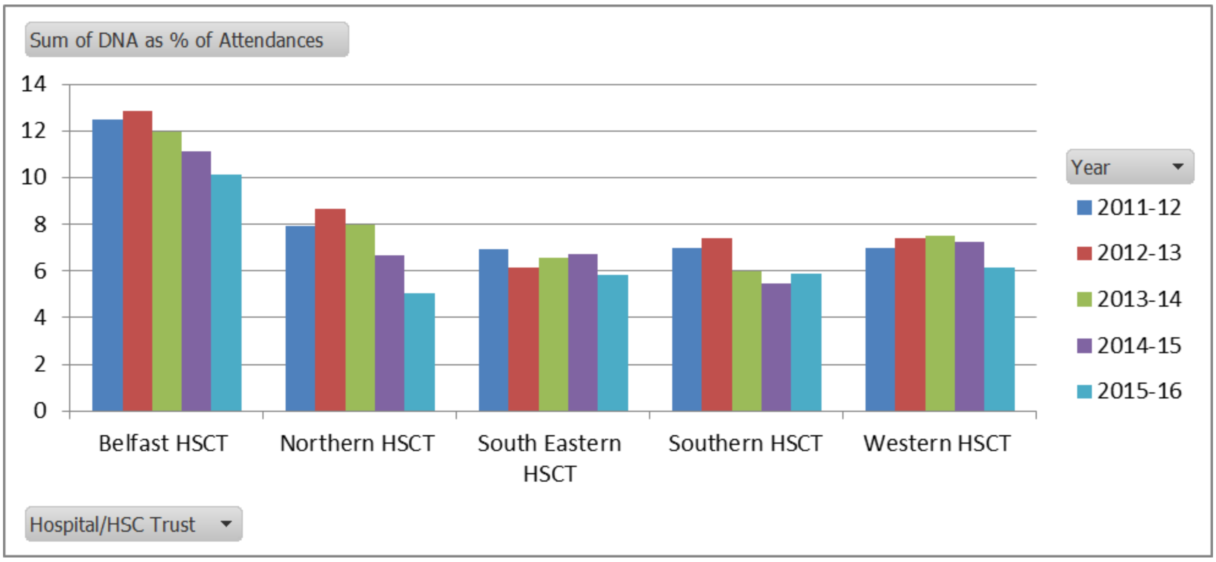


Figure 7.5.8 – Did Not Attend appointments as a Percentage of the attendees count (Source data: Department of Health, 2017, Outpatient Activity)

Similarly CNA's are highest in the Belfast Trust but equally the Northern Trust is substantially higher than the other 3 trusts for CNA. Notably the Northern Trust were one of the best performing trust at DNA which may indicate an ability to reduce DNA's by possibly moving these to CNA. While not ideal a CNA still is better than a DNA and provides opportunity to rearrange appointments and make use of later stage appointment slots. Some potential exists to explore current best practice in the Northern Trust.

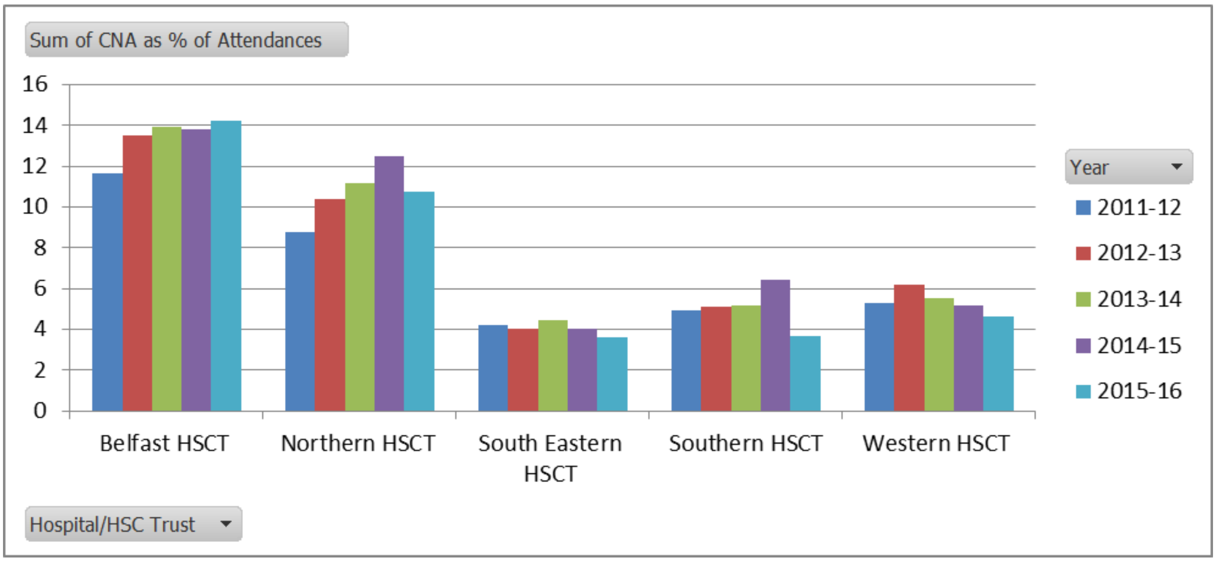


Figure 7.5.9 – Could Not Attend appointments as a Percentage of the attendees count (Source data: Department of Health, 2017, Outpatient Activity)

The hospital cancelations, unlike the DNA/CNA, are the responsibility of the hospital. The figures in figure 7.5.10 highlight significant levels of cancelations. In particular Belfast in 2011-12 and 2012-13 has high level of cancelations. The cancelation represent a significant level of patient dissatisfaction and not delivering value as the appointment will have been deferred to another time leaving a vacuum in the patients expectations. These also lead to a longer "wait" which represents one of the key definitions of classic Lean waste. The delay will also absorb additional resources in managing and administering the waits.

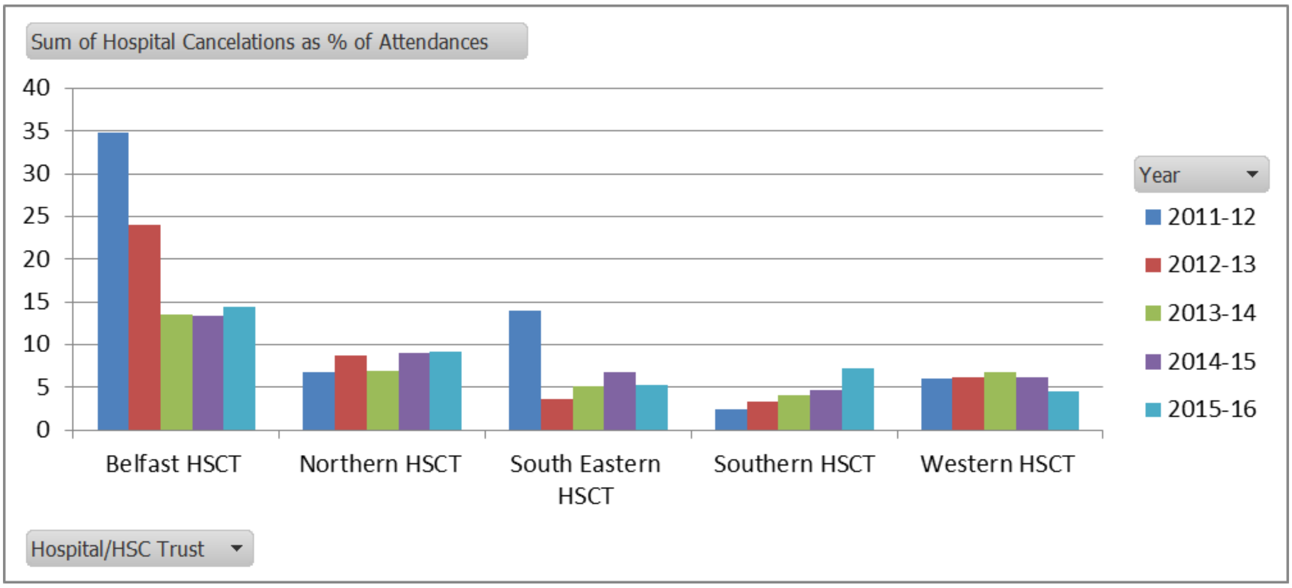


Figure 7.5.10 – Hospital Cancelation Appointments as a Percentage of the attendees count (Source data: Department of Health, 2017, Outpatient Activity)

Taking into account the three areas of waste, the table 7.5.5 analysis combines all of the appointments both new and reviews and all of the new and review categories for DNA, CNA and hospital cancelation. The analysis then considers that for every successful appointment how many appointments are unsuccessful. The Belfast trust in 2011-12 and 2012-13 has substantial figures which were initially identified as significant outliers in the cancelation chart previously. These have been highlighted in red below and what this analysis shows that in the two highlighted years for every successful appointment 1.5 and 1 respectively were unsuccessful either by patient or hospital. What was not clear until the below was completed was that the Norther trust had reached a higher level more comparable to Belfast in 2011-12 and the Western Trust has displayed a higher peak in 2015-16 which had not been evident in the other figures. The reason that then became evident was when it compared successful volumes alongside unsuccessful volumes which had initially been masked by the overall higher volumes of the other hospital trusts. This is highlighted in amber below. Note that the rest of the figures are not highlighted in green to reflect success as although these are lower number the number still reflect failure and waste in the system rather than patient value.

Table 7.5.5 – Ratio of Unsuccessful Appointments to Successful Appointments

	2011-12	2012-13	2013-14	2014-15	2015-16
Belfast HSCT	1.5	1.0	0.8	0.7	0.7
Northern HSCT	0.6	0.5	0.4	0.5	0.4
South Eastern HSCT	0.4	0.2	0.2	0.2	0.2
Southern HSCT	0.3	0.3	0.2	0.3	0.3
Western HSCT	0.2	0.2	0.2	0.2	0.8

The reason for cancelations, as shown in figure 7.5.11, provides some early insight as the HSC trusts are only beginning to measure this. The full data set is not available for the 5 years and the data that is available is incomplete. Initial data sets had a large % of data lines with missing reasons codes and efforts are underway to address the data gaps going forward.

To give a snapshot of the type of information available the 2016-17 data for the Belfast Royal Victoria recorded the following reasons for cancelation.

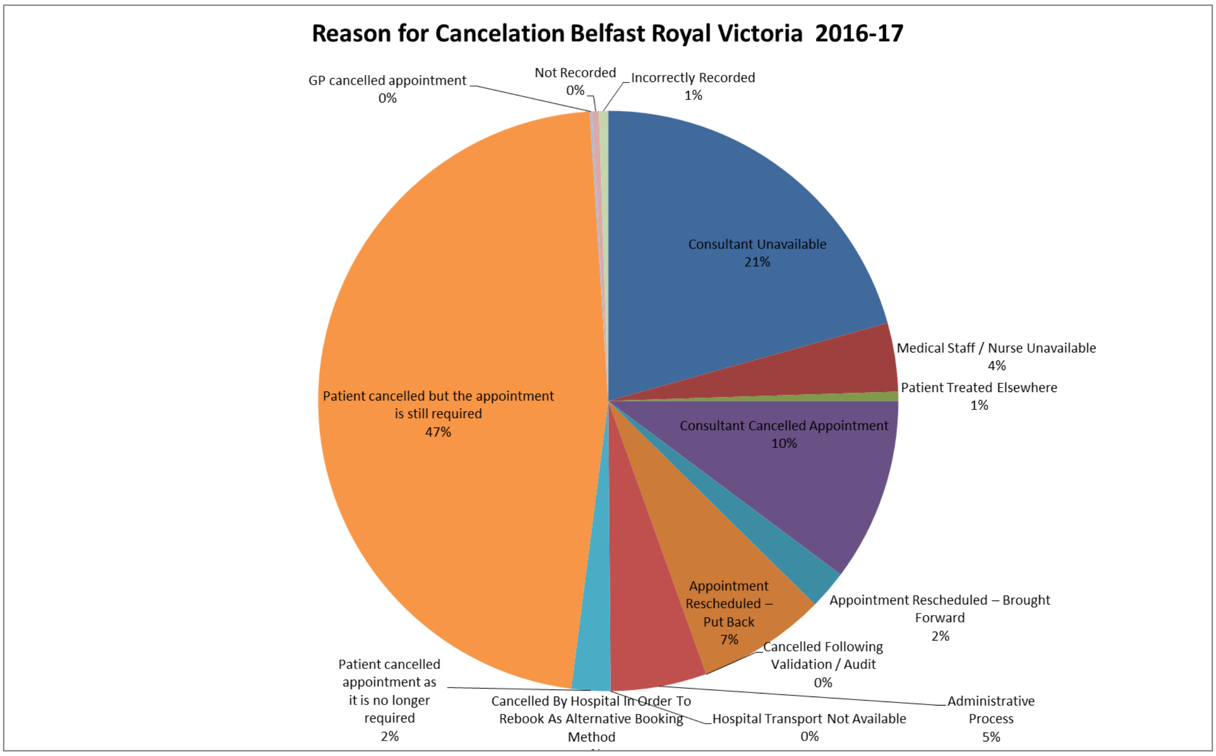


Figure 7.5.11 – Reason for Cancelation of Appointments in Belfast Royal Victoria Hospital

Summarising the cancelation one can find that comparisons across hospitals has some benefit in identifying trends. This must be viewed with the caution of not assuming that the lowest number reflects value for the patient. The longitudinal data profiles across years can be useful in identifying trends and evidence of changes in practice, response to interventions and changes to funding but they can mislead in assuming lower numbers represent value. Lastly comparisons of success and failure can bring some level of context to the value discussion which is lost in the larger trend information. This could be useful in putting a value and context on waste.

7.5.3.4 Inpatient Waiting Times

Similar to analysing the outpatient waiting times, the data was processed to convert the waiting categories and patient counts to a total number of days waiting. This is not typically done and comparisons across years are not frequently completed. The data has again been processed to use a mid-point of a time category. There was also some grouping of categories across the 5 years as the year on year categories varied to meet internal reporting issues.

7.5.3.4.1 Cardiology Inpatients

The data analysis provided a calculation that in the last (Dec 16) reporting quarter **43,451** days are used in Northern Ireland waiting for inpatient appointments across the 5 HSC trusts. This equates to an average wait time of **114 Days.** The single quarter is reported as it is not possible to identify unique patients across the 5 years to calculate the total days waiting over this time. A patient waiting in the quarter may also be in the next quarter's figures and this could represent double counting if you multiply across quarters or years. There is a substantial difference between Belfast and any other HSC trust in the figures. This may be related to the Belfast Trust being a regional centre for cardiology. In addition some of the patients will be captured as day patients.

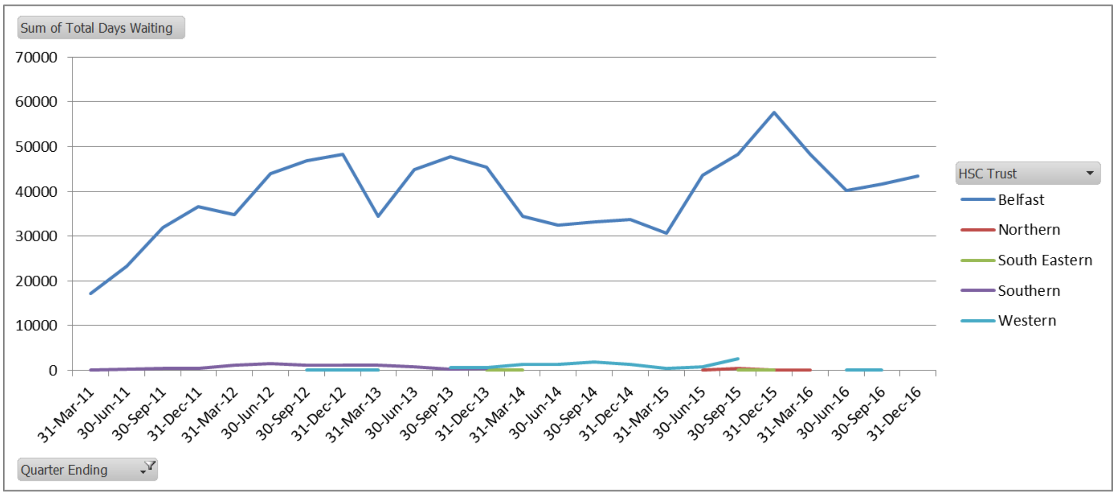


Figure 7.5.12 – The Number of Cardiology Patient Days Waiting Inpatient Treatment (Source Data: Department of Health, 2017, Inpatient and Day Case Waiting Times)

Further analysis of cardiology day cases as an alternative to inpatients hospital stays was completed. The day case patients are waiting a total of **222,325** days on the 31 December 2016 which meant the average a patient is waiting **104** days. Charting the figure over the 5 years highlighted large changes in late 2013 and through 2014 which are shown in figure 7.5.12 raises questions about lessons learned and the apparent loss of these performance levels.

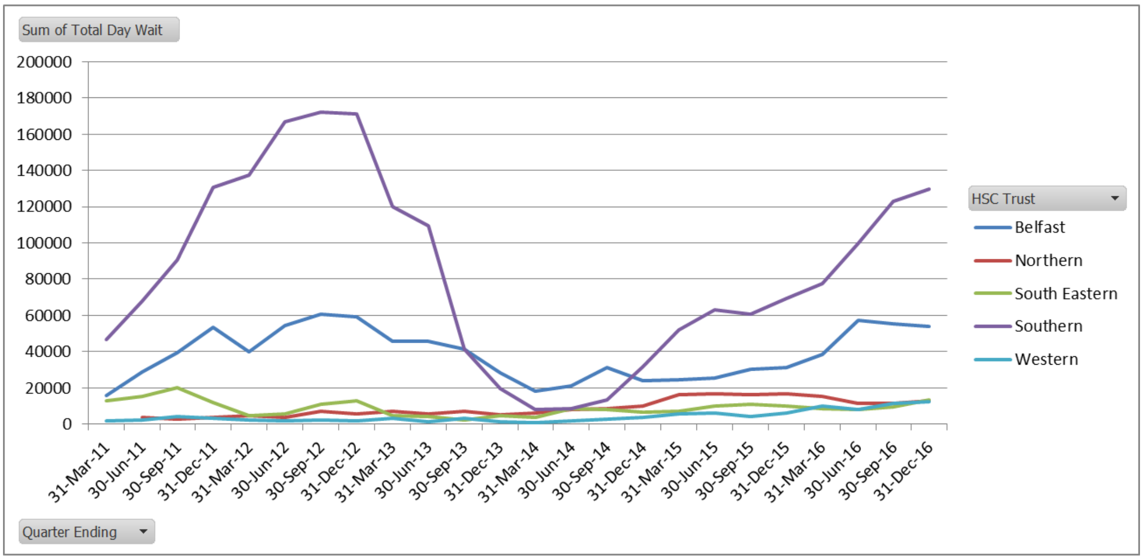


Figure 7.5.13 - Number of Cardiology Patient Days Waiting for Day-Case Procedures (Source Data: Department of Health, 2017, Inpatient and Day Case Waiting Times)

Cardiac surgery similarly has a waiting list but this is uniquely Belfast as the regional specialism during the time period.13, 624 days are used waiting across all patients in the December16 quarter hospital data returns. The average wait is 63 days.

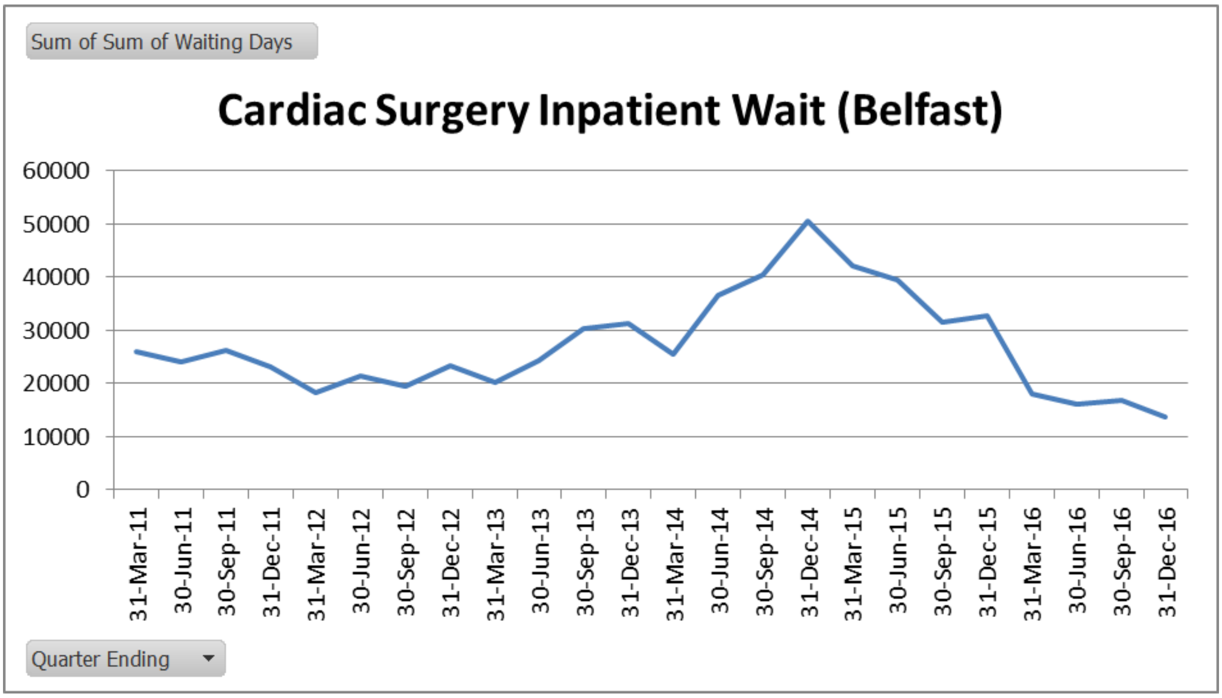


Figure 7.5.14 - Cardiac Surgery Inpatient Waiting Days (Source Data: Department of Health, 2017, Inpatient and Day Case Waiting Times)

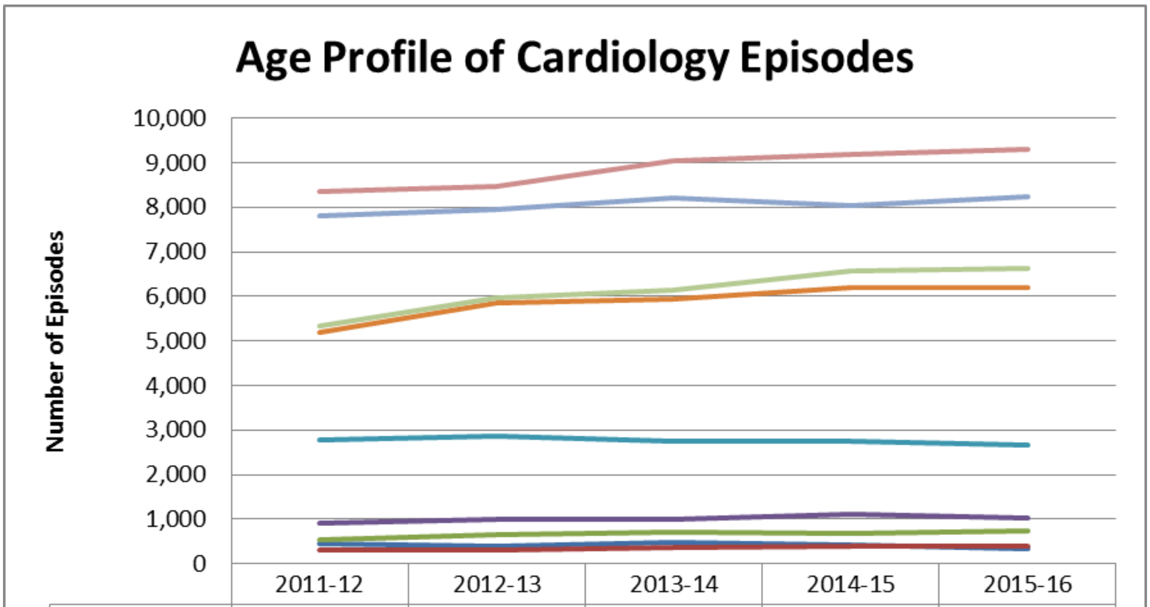
7.5.3.5 Cardiovascular Disease in the Context of Hospital Activity

The area that this thesis has selected is cardiovascular disease. This is an area of significance as it represents two of the three largest reasons for readmissions and has one of the largest specialisms in hospital based care. The assumption therefore is that an intervention in cardiology will have a large impact on the overall performance on a hospital. The data in table 2 in appendix 7 however puts some context around the volume of activities in a hospital. The reason this is highlighted is to ensure that cardiovascular reform or changes are taken within the context of the overall workload of the hospitals.

What is clear is that the hospital system is made up of a large number of specialism. Focusing on a single patient pathway within the hospital will result in improvements within 5.7% of the overall activity. What it will not result in is large scale reform impacting significantly across the system. In cardiovascular disease a hypothetical 50% reduction in bed utilisation, removing weeks from the waiting time or removing 50% of the waste activities will have an impact on individual patients and substantial costs but this is not going to reflect a significant change across the system as ultimately this will be a 50% improvement of 5.7% of the activity. This however must be balanced with understanding that the huge resources being invested in healthcare as NHS England in 2016 had a £120.516 BN (NHS Confederation, 2017) spend. This means that even small changes have large impacts on the national budget as Health consumes a disproportionately high % of the National budget. Two points emerge in considering this, firstly can learning from the cardiovascular disease care pathway be transferred to other conditions and specialisms or are they limited and secondly is it better to focus on a pillar specialism or the platform across the system to make the best impact.

7.5.3.6 Demographics of Cardiology Patients

Open data available focused on the episodes of care includes age information which allows analysis of the profile of the patients. Over the period of the data the average age for the patients increased by 1 year from 64 to 65. This is relevant as global trends reflect an ageing population. The age profiles of a service can have an impact on the service design, consideration of what value means for a patient and the patient’s ability to respond to new technologies. The male to female ratios of patients also changed by 1% as 38% of the patients were female at the beginning and 39% at the end. Similar to age, sex has implication on the personalisation of care as factors such as female medical conditions; response to medication, presence of dementia, and responsiveness to technology will have a relationship between age and sex. These may not be direct correlations but will become relevant in risk profiles such as likelihood to embrace technology monitoring at home.



	2011-12	2012-13	2013-14	2014-15	2015-16
Age 0-9	439	389	467	419	350
Age 10-19	315	309	361	396	390
Age 20-29	538	666	710	690	735
Age 30-39	899	997	989	1,100	1,021
Age 40-49	2,792	2,854	2,738	2,751	2,661
Age 50-59	5,180	5,840	5,944	6,204	6,189
Age 60-69	7,797	7,941	8,195	8,031	8,252
Age 70-79	8,347	8,456	9,038	9,189	9,311
Age 80+	5,328	5,968	6,140	6,578	6,639

Figure 7.5.15 – Age Profile of Cardiology Episodes – Line Graph (Source Data: Department of Health, 2017, Acute Episode Activity)

The largest volume decline was in the 40-49 categories which had 131 less episodes and biggest increase was in the 80+ category with 1311 extra episodes. The learning from the analysis over the 5 years is that 3913 extra episodes took place in 2015-16 compared to 2011-12. This is not frequently used as a measure as the data is provided for an individual year with less focus over the year on year trends.

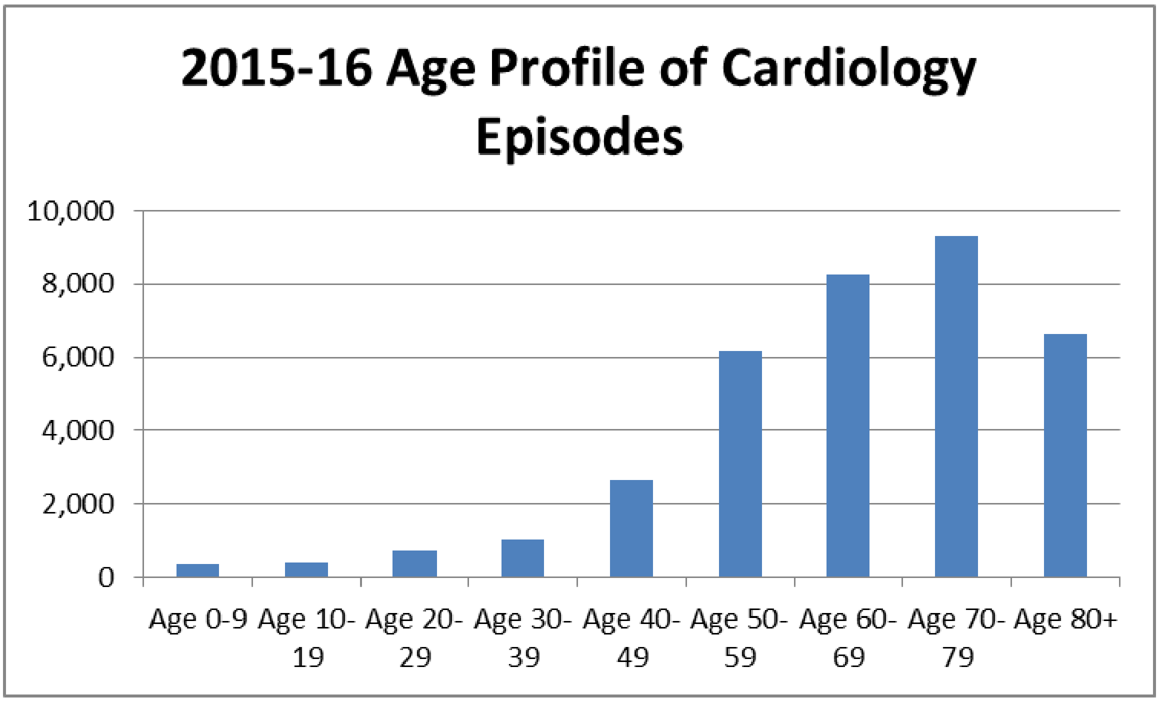


Figure 7.5.16 – Age Profile of Cardiology Episodes: Profile (Source Data: Department of Health, 2017, Acute Episode Activity)

Figure 7.5.16 provides further details on 2015-16 to provide a profile of the age of patients. The diagram highlights that while the year on year comparisons show growth in the younger ages, over 85% of episodes are with patients over 50 years old. Only 8.2 % were below 40 years of age. Again this raises question about the focus on Lean and healthcare technology and can it respond to the wide variety of needs and challenges that could impact the vast majority in the 50+ but also address the 8.2% below 40. In the qualitative analysis the Northern Trust focus group frequently referred to “elderly-elderly” to differentiate between people who were perhaps retired but reasonably mobile and those with more extreme frailty and elderly. This is not well defined in age categories but reflects the front line experience of a number of client groups with various distinct needs that not reflected in age breakdowns alone.

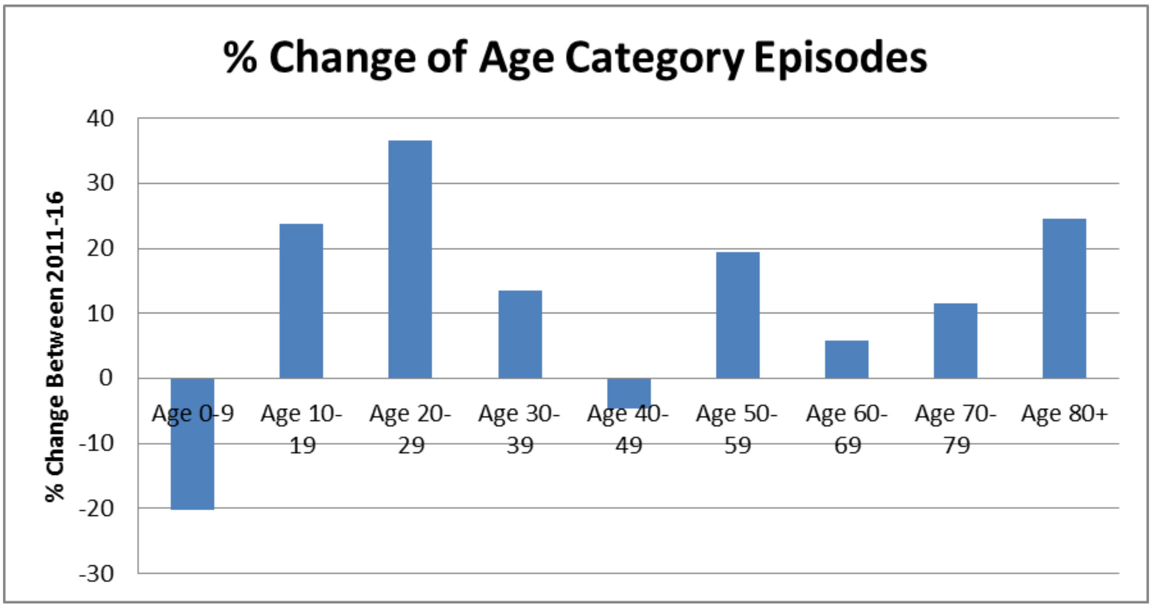


Figure 7.5.17 – Demand Changes of Age Categories – 2011-2016 (Source Data: Department of Health, 2017, Acute Episode Activity)

Over the 5 years there is clear evidence of change both positively and negatively as shown in figure 7.5.7. Smoking bans in public places (2007), rising obesity, reduced physical activity, changes to clinical intervention or medicines all have potential impacts. It is not the purpose of this thesis to provide root cause analysis of the changes but highlight the Lean root cause analysis potential through Lean tools. The Lean and healthcare technology solutions must reflect a personalisation of care understands the diversity of reasons to make an impact on the health outcomes.

7.5.3.7 Emergency Admissions

Emergency admissions are a key measure for healthcare systems as an emergency is an unplanned admission. Initially one can look at the data and note a degree of stability in the numbers with a slight decline over the 5 years. This however needs to be taken in context of a number of other changes during the period. Firstly the volume of admissions to hospital during this time had increased 8% in total over the 5 years therefore the volume of emergency admission was against a higher total. This is illustrated in 2012-13 where despite a significant growth in the total emergency patients by 344 patients, the percentage of the total patients fell from 31% to 30%. Secondly the biggest impact that emergency patients have is in removing resources from planned activity. Section 7.5.3.3 discussed the hospital outpatient cancellations and during the period there was overall reductions in cancelations but these were not replicated across all trusts as some increases were seen in the Southern trust. While it cannot be seen in the data available there could be further exploration to collect data to understand the relationship between emergency and cancelations.

Lastly the level of stability in the emergency figures is an interesting point. One of the key principles of Lean is about designing a system that "pulls" to customer demand (Womack 2010). The assumption behind most healthcare system design is that emergency is unpredictable and therefore difficult to plan for. The figure highlights that a degree of predictability and therefore planning is possible that could address and impact on the levels of cancelation in the hospital. This degree of stability also reflects some challenge that the root cause of emergency is not being addressed and there continues to be opportunities to identify patients earlier and move them from emergency to planned admissions. This will be much wider than a hospital issues and reflects the overall care pathway of patients at risk (public health), patients in general practice, patients on waiting lists and routes to appropriate care.

Within this are significant issues in missing data as we are not clear for example about how many patients on a waiting list ended up as an emergency admission or if technology or process could be used to identify escalation in a patient condition that will result in an emergency patient.

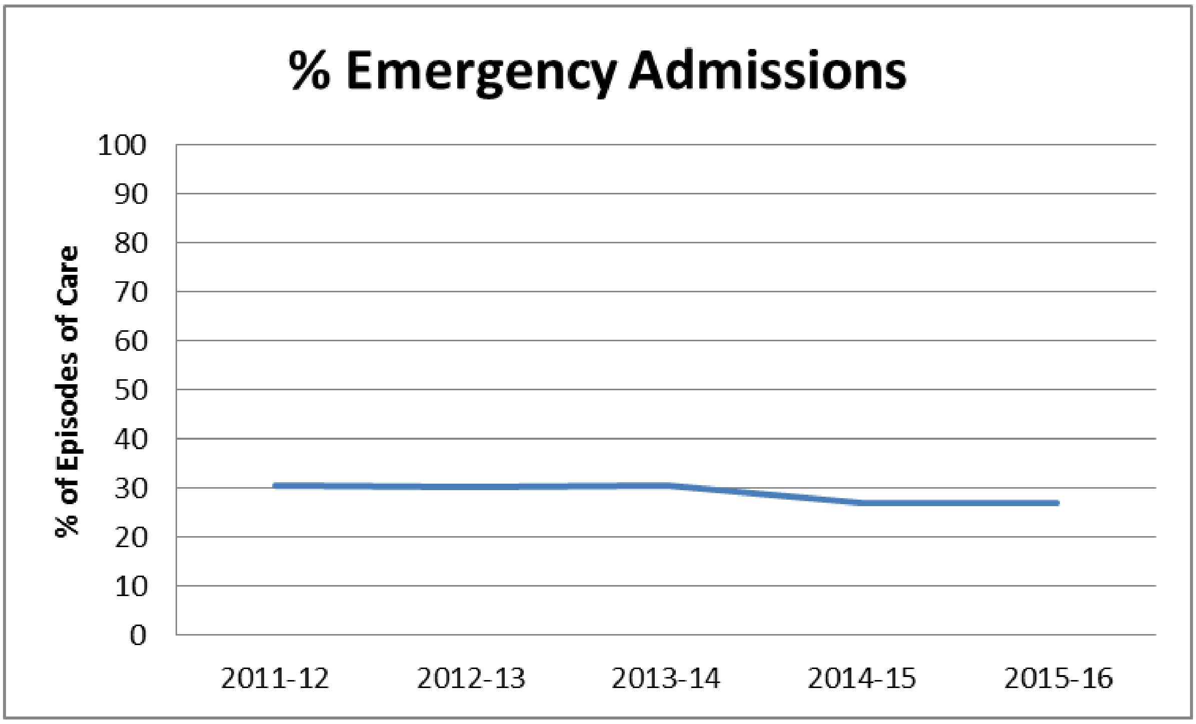


Figure 7.5.18 – Emergency Admissions (Source Data: Department of Health, 2017, Acute Episode Activity)

7.5.3.8 Bed Utilisation for Cardiovascular Patients

The episodes of care for cardiology also provide a level of detail about the bed days used by cardiology patients. This is relevant as bed days utilisation impacts the overall flow of a hospital and impacts on waiting time. The analysis in figure 7.5.17 shows a worsening position but what this masks is that from 2012-13 through till the 2015-16 period the average number of bed days used per episode of care had reduced from 3 in 2011 to 2. These figures however reflect a high level statement which would not translate to specific patient groups or procedures.

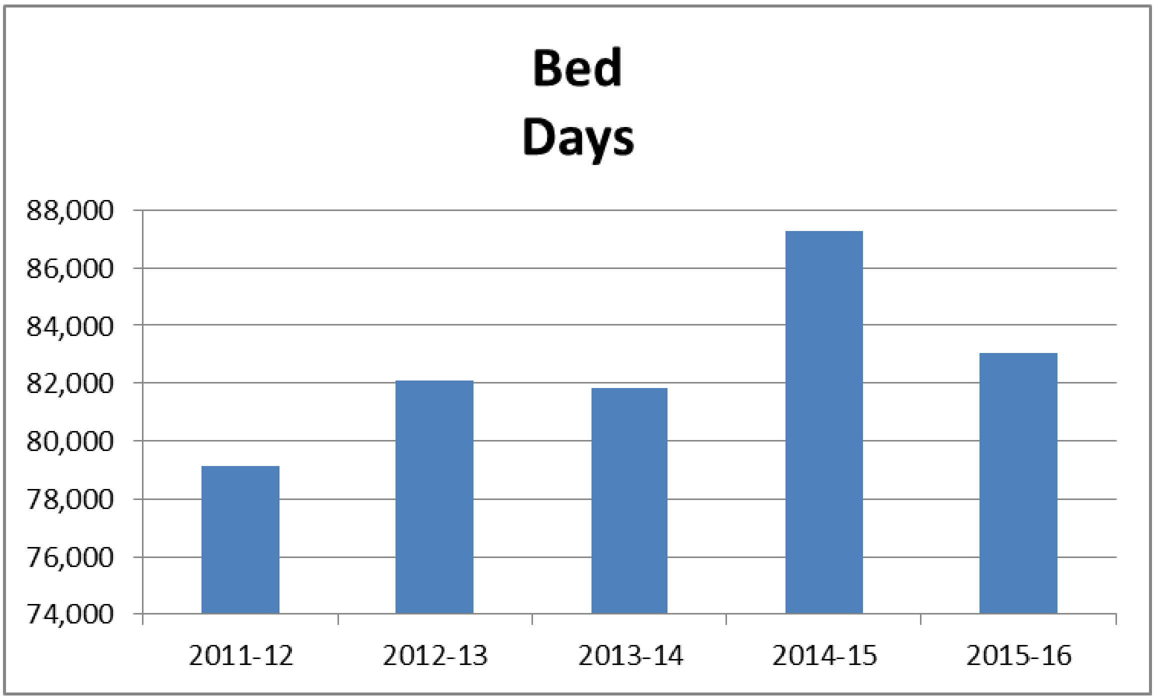


Figure 7.5.19 – Bed Utilisation Days (Source Data: Department of Health, 2017, Acute Episode Activity)

To provide a finer level of detail there need to be a breakdown of the specific diseases and conditions that are being managed within the system in order to make a more informed analysis. The following highlights the primary diagnosis episodes of care related to cardiology as being defined as “Diseases of the Circulatory System”.

A Pareto Analysis or Pareto charts is one of the common quality improvement approaches and in this case identifies the bulk of the bed days by a category. By using the diseases of the circulatory system the analysis highlights that just over 81% of the bed days are accounted for by 3 diseases. This separation between the bed days and the finished episodes is particularly important point as bed days are often a direct proxy of cost. In a reform initiative the tendency would be to chase the volume of episodes without considering the costs and patient impact in the system. Pareto analysis has drawn a new conclusion to highlight that any significant improvement in these three conditions will provide a significant return.

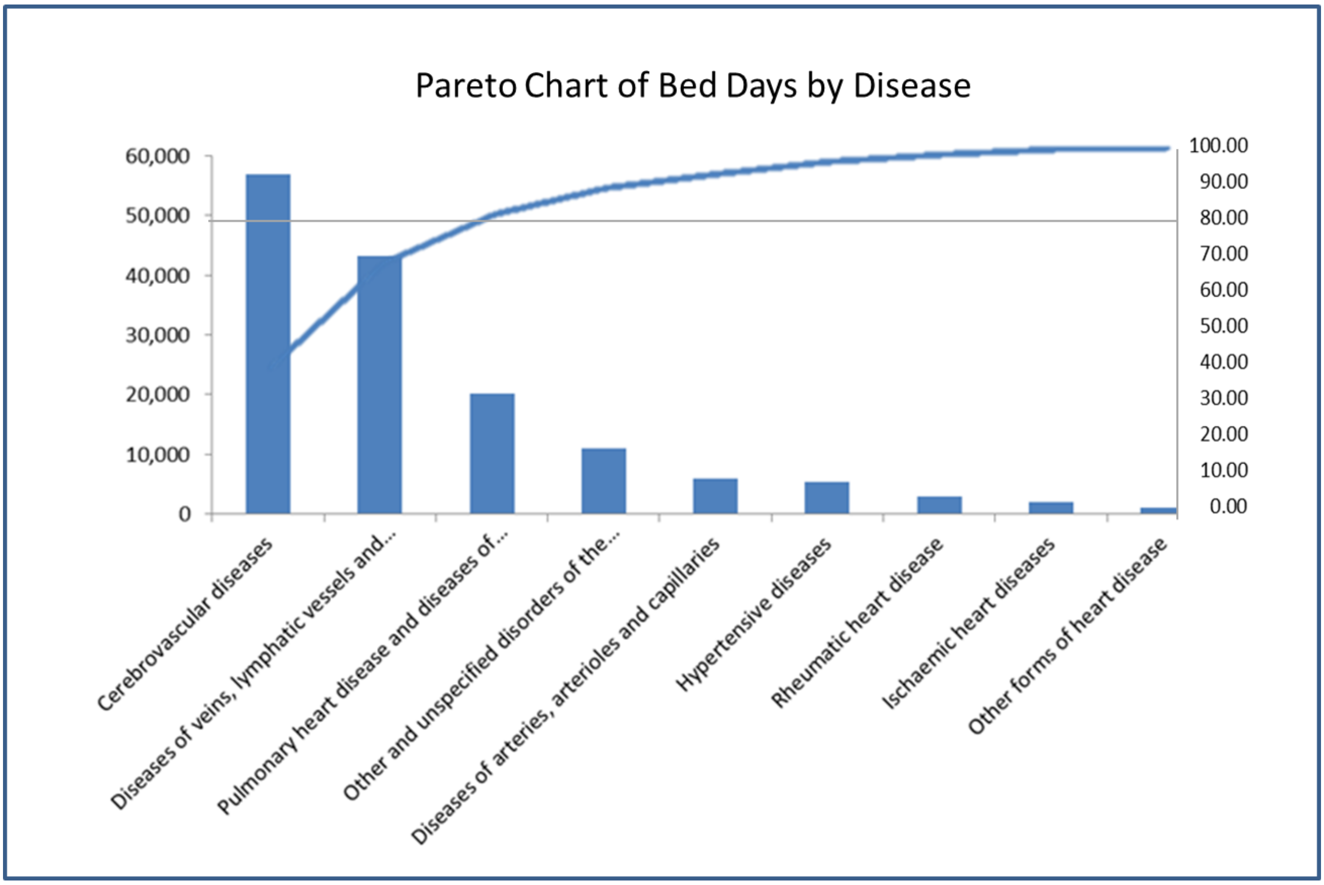


Figure 7.5.20 - Acute Programme of Care: Primary Diagnosis Pareto Analysis Chart (Source Data: Department of Health, 2017, Acute Episode Activity)

7.5.3.9 What Data is Not Captured?

There is a lack of long term outcomes measured in all of the data. Linked to this is an absence of value based decisions measured to reflect quality from the patient's perspective. The data that was used was open source and anonymised data which means that the number of engagements a patient has with care providers is not possible. This would be useful to see if this is changing as an ageing population has to interact with multiple care providers. Finally there were also limited cost measures available in open data sets.

7.5.3.10 HSC Feedback on the Analysis

The research methodology was a mixed method approach and significant data had been gathered. There was also a risk that although the analysis may bring some insight on a question or challenge the operational providers may discount the evidence as being irrelevant or the underlying data as being flawed. To explore these potentials the Ulster University provided an opportunity to present a summary of the thesis to an MSc Innovation Management class made up primarily of healthcare leaders through a workshop. This was an exceptional opportunity and built on feedback from presenting at the

- International Conference on Engineering, Technology and Innovation in 2015
- European Lean Educators Conference in 2016

While the previous presentations were peer reviewed from experts in technology and lean, this group represented experts from a healthcare setting. They also had the ability to challenge the healthcare position and the Lean as this included experts with significant experience of performance management within healthcare. They were also very familiar with the data being presented as this was sourced from their healthcare organisations. The attendees and roles of those taking part on the 25 October 2017 are included in appendix 5. The overriding comments from the feedback was that they did not have access to the level of information across the value stream, they agreed that there was opportunity and their understand was that there would opportunities to use this approach however the tools to either view this level of information or analyse it were not available to them.

In summarising the analysis of data within the hospital based care discovered significant waste in form of waiting with such as;

- Outpatient waits of 109 Days
- Inpatient wait of 114 Days

- Day patient wait of 104

Measure which gather the total waits for all patients highlight a significant growth in the number of days patients across Northern Ireland are waiting. Within these waits there are trigger point dates that appear to escalate issues which suggest underlying issues beyond the ageing population. Viewing the full patient journeys may assist in commissioning decisions which could be influencing changes in patient volumes and waits. High levels of unplanned admissions indicate waste within the system yet there is heavy variance in the new to review appointments ratios suggest lessons learned could be quantified and repeated across the HSC trusts. Cancelations both from the patient and the hospital are a significant scale and indicate potential room for improvement. Lessons learned from understanding the patient population may assist in personalisation of care and interventions that could assist in improving care and addressing waste such as missed appointments.

Cardiovascular disease although significant in the operation is only a small piece of a large complex system and reforms should consideration if focusing on fixing one patient stream or alternatively one cross cutting element of the whole system would have bigger impact. Some caution on the use of data was also evidence as internal trusts measures for the quality of the data have changed over time. The ability to sustain improvements was a significant qualitative feedback and the consideration of technology within this was welcomed as an approach.

7.5.4 Lean Wastes/ Lean Non-Value Add Activities

This section explores Lean failures in healthcare identified from the literature review in Chapter 3 for hospital related activity for cardiovascular disease patients.

Table 7.5.6 - Literature Review Lean Waste Categories Aligned with Cardiovascular Disease: Hospital Based Care Focus

Healthcare Failure Area Identified in Chapter 3	***Evidence in Cardiology***
Waiting times	• Documented evidence of growing outpatient waiting times. Some consideration to be given to changes in commissioning leading to expanding waiting lists. • Documented evidence of growing inpatient waiting times.
Diagnostic	• Patients with an undiagnosed heart condition (structural or congenital condition) lead to unplanned interventions. (Yock, 2015)
Medical Complexity	• Patients with a number of long term health conditions can result in conflicting treatment – chronic kidney disease, diabetes, cancer and asthma evident in the causes of readmission literature often linked to the medication conflicting and causing symptoms (Emerged in qualitative analysis – Cardiology focus group).
Additional Healthcare Visits	• Inconsistent number of review appointments leads to questions on over-processing or under-processing patients in certain hospitals.
Co-ordination of Healthcare resources	• Readmissions reduction requires coordination of service provision to ensure the patient has all requirements covered. Evidence of heart failure nurses being unaware of readmissions before their scheduled appointment. (Emerged in qualitative analysis – Cardiology focus group).
Stress/overload of staff	• Demand is significantly outstripping capacity therefore waiting lists.
Repeated Procedures	• Readmissions as a key repeat of procedures.
Length of Stay	High ALOS related to Heart Failure patients. Opportunity to

	consider alternative models which have been successful in maintaining quality outside of hospital.
Cost	Readmissions results in additional costs to the system. USA Medicare and Medicaid programme financially penalise hospital for readmission.
Quality	• Clinically related quality issues such as recoiling of angioplasty, scarring called restenosis, AF treated with stroke medication with some side effects of bleeding, scar tissue associated to stents resulting in more surgery, stents introduced to balloon to address issue, ttransplant rejection and patient takes a stroke related to surgery (Yock, 2015) • Readmissions of patients can be regarded as a quality issue in a number of cases. Further treatment is required as the underlying issue has not been addressed or the therapy which has been provided is not suitable to address the condition.
Emergency Admissions	High levels of unplanned admissions.
Death	• High levels of cardiovascular disease related mortality. • Failure to consider the adoption of palliative care for patients who have signs that this may be the best course of action. Result is that a patient may be treated for surgery or aggressive intervention that won't benefit the patient but cause distress. (emerged in qualitative analysis with cardiology focus group)
Infections	Infection related to some of the reasons for readmissions. In particular hospital acquired infection is a specific waste.
Emerging from this research and not covered in Lean Healthcare Literature	• Lack of Continuous Improvement - due to the drive for cost cutting any innovation has focused on either proof of service delivery, addressing a target or reducing costs with limited focus on continuous improvement. • Limited use of technology to complement service delivery outside of hospital.

	• Limited use of data to personalise and inform the care needs • Personalised therapies and interventions not widely understood and lacking evidence • Non-value from monitoring of patients who are responding to treatment and don't require further intervention.

7.5.5 Discussion on the Hospital Based Care

As research question one addresses Lean for long term conditions we find that the outpatient clinics are the source of expertise related to the condition. These are important areas to analyse as patients are requiring a longer engagement throughout their life. As patients' lives longer with a condition there is a question of how to support a patient requiring specialist insight for a long term and if the outpatient clinic is designed to manage this level of patient engagement. What we can't see in the data is the number of engagements a patient has over their lifetime and if this has increased as patients are living longer. Lean may have some options of considering this new type of demand and the implication on service design and the fitness for purpose of the traditional outpatient clinic. In the literature; Patel et al.(2008) , Mendoza et al.(2009) and Tibaldi et al.(2009) provide clinical trial evidence against alternative models of care in hospital at home type service design. There are Lean options of redesigning the outpatient service to address long term conditions or upskilling of the GP to be able to address specialist cardiology based monitoring and interventions and therefore reducing the demand on outpatients.

Additionally, research question 2 explores the non-value add activities and it is important to analyse the emergency admissions which could have been avoided as non-value add activity. Two pieces of the analysis stand out in the non-value add activities, one being the high levels of unplanned admission and the other being the long waiting lists for outpatient and inpatient service. Lean can define both of these as waste but there is limited evidence of attempts to address this waste as there is a culture of accepting that waits and a public health system are connected. Reform initiatives focus on putting a target on the waste of a number of weeks but this fails to address the patient value perspective and fails to consider opportunities to change the approach based on intelligent data and potentially reducing demand. For example, data was not available about the number of patient who admitted as an unplanned admission but was on the waiting list. There is potential to utilise data to bring an intelligent waiting list which prevents an unplanned admission. The technology options will pick this discussion up later but from a Lean perspective the waiting lists are wastes, current measurements are not reflecting patient value and continuous improvement is focused on a system derived measure rather than patient value.

This leads to the third research question addressing the area of redefining value from a patient perspective. As technology enables the provision of healthcare monitoring remotely, the blend of Lean addressing quality and patient value will be important to ensure that patient value is considered alongside clinical outcomes and cost. Technology also has a role on measuring missing data on the longer term effectiveness of treatment which can feed back to measurements of outcome effectiveness for treatments.

7.6 Medicines

The previous section of the thesis analysed hospital based care for cardiovascular disease patients. This contributed to the aim of the thesis by analysing the role of Lean thinking application to integrated healthcare patient pathways. In figure 7.2.1 and duplicated in figure 7.6.1 below one can see medications prescribed is the next set of activities within the patient value chain. The medicines interventions have a series of activities but these are only a small part of understanding the implications of their use.

The use of medicines rarely emerges in Lean literature except in its manufacture or dispensing. The cost of medicines, misuse and failures creates a fertile area for the research questions of this thesis. This chapter provides an overview of the medicines prescribed for cardiology and explores the Lean values, waste and emerging technology related to medicines.

Medicine is being analysed within this chapter as a separate entity, however medication is an intervention throughout the patient flow. Patients may be given medication at the GP to deal with presenting symptoms and these medications can be amended, changed, added to or stopped as they progress along the pathway. Patients needs will also change as they age and other health conditions are detected. The analysis of medication prescribing in this section will reflect on these various interactions.

As the aim of the thesis includes understanding the integrated healthcare pathway, it is appropriate to review medications impact to continue addressing the research question of how Lean can be adapted for long term conditions. This will include analysis of the activities and services that may be related to Lean wastes. It will continue to use cardiovascular disease as an example of a long term condition to provide focus and application.

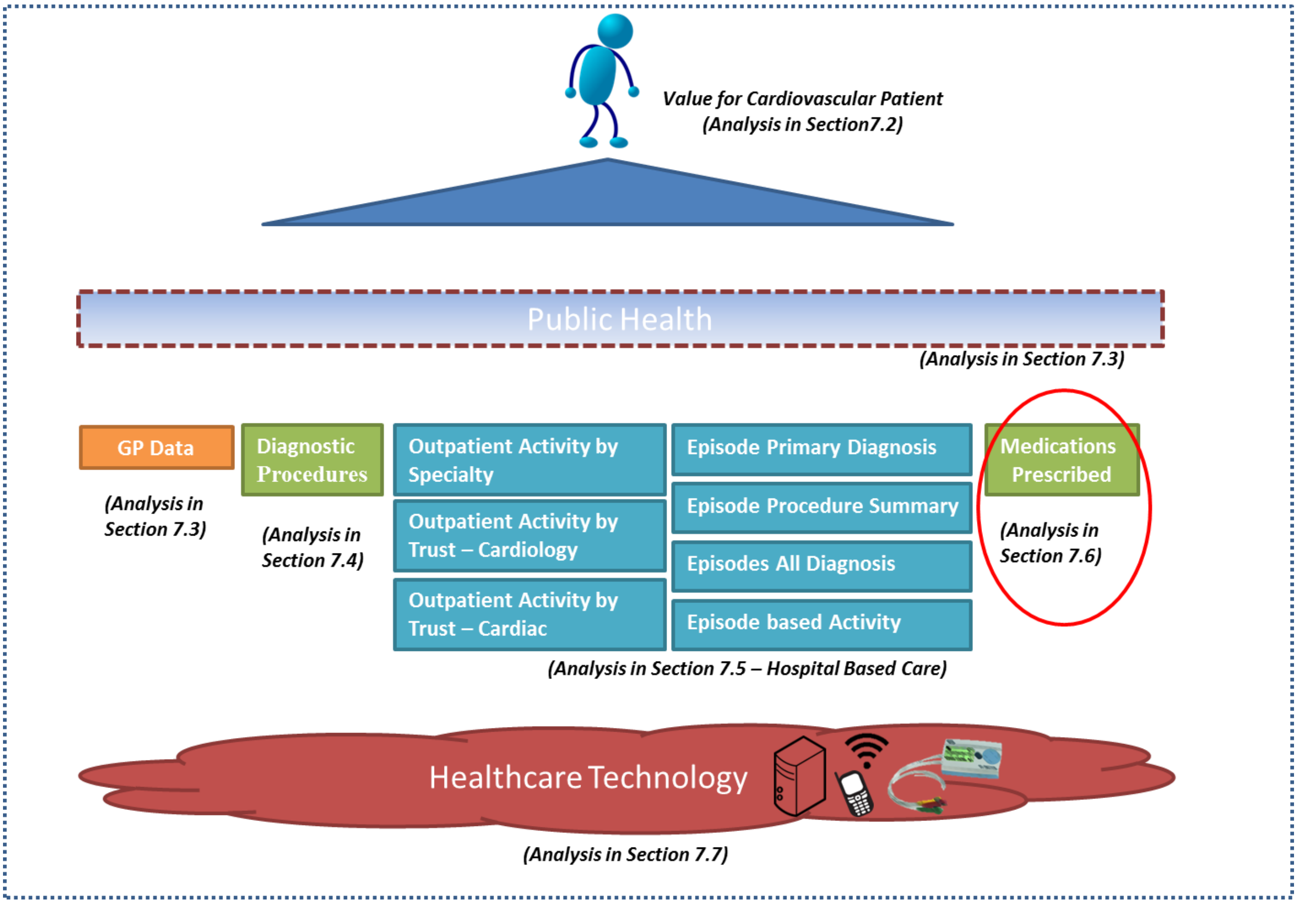


Figure 7.6.1 – Cardiovascular Disease Data Set – Focus on Medication

7.6.1.1 Medicines Definitions

Medicines used within the UK are classified through a standard called the British National Formulary (BNF). The BNF groups medicines for different conditions together with each grouping referred to as a chapter. Chapter 2 of the BNF is dedicated to cardiovascular system medicines which aligns with the focus of this thesis. The BNF chapter definitions are used widely on reporting medicine within open data information available in Northern Ireland. The BNF chapters, sub categories and detailed categories are broken down as shown in Appendix 7- figure 1.. The breakdown from chapter through to detailed categories allow medicines to be grouped and makes it easier for clinicians to understand the type of drug and its purpose. GP's and clinicians can therefore consider the risks and impacts of the various medications on the patient prior to selecting the drug they believe to be most effective with least side effects. This thesis will not analyse the clinical decisions around specific medication but looks at the trends, outcomes and costs associated to various decisions in the care pathway.

7.6.1.2 The Role of Medication

The use of medication is primarily to reduce patient risk of a clinical event, to manage an existing condition, to treat conditions, to reduce symptoms or alleviated pain. The use of medication has expanded significantly both in volume and cost, related to this is the growth in the potential for delays and prescribing errors (Ker et al., 2014). Cardiovascular disease is a high user of medicines throughout the care pathway including all stages from prevention through to treatment. As many patients suffering from cardiovascular disease are elderly, the patient may have a number of conditions and therefore will have medication for a number of conditions which is referred to as polypharmacy.

7.6.1.3 Future Development of Medication

Medicines optimisation is the main term used in the Northern Ireland "Medicines optimisation quality framework" (Department of Health, 2017). This focus on optimisation was reflected in the establishment of a Medicine Optimisation and Innovation Centre (MOIC) at Antrim hospital. The framework presents five rights of medicines administration which are;

1. The Right Patient
2. The Right Medication
3. The Right Dose
4. The Right Time and Frequency of administration
5. The Right Route

Qualitative discussions with the authors of the framework and the leads of the MOIC revealed that technology was at the centre of many of the future plans with trials ongoing or supporting medicines adherence and electronic prescribing. Beyond the operational improvements aspect, research is ongoing into the use of medicines in the prevention or reduction of the risk of cardiovascular disease (Yusuf et al., 2016). The term personalisation (sometimes referred to as precision) is used in many medication discussions for the future around using genetic information to target medication. For example Innovate UK, a government funder of future industry has established a number of large investments for the UK within centres known as Catapults (Innovate UK, 2016). One of these is a precision medicine Catapult.

7.6.1.4 Medication Analysis in This Thesis

With the definition, role and future direction explained, the remainder of section 7.6 will reflect the common approach of use in the previous sections of 7.2, 7.3, 7.4 and 7.5 by analysing;

- Current role for cardiovascular disease medicines in academic and grey papers
- Current measures and data within the Northern Ireland healthcare system
- What is not measured
- Cardiovascular disease medicines activities against the Lean non-value add activities identified in academic literature in chapters 2-4.

From this analysis, the thesis can contribute to answering the research questions of how Lean can be adapted for long term conditions (research question 1) and contribute to identifying methods for health technology to address Lean non-value add activities (research question 2). The analysis will also build some insight into addressing where health technology can assist in redefining patient value which reflects research question 3. It should be noted that the open data utilised in medication is sourced from procurement related organisations rather than care provision data. As its purpose is somewhat different it can mean that there has been less analysis of its use in care provision.

7.6.2 Analysis of Cardiovascular Disease Medicines through Papers and Grey Materials

There is a significant wealth of papers on the creation and use of medication in general healthcare literature but very limited academic work linking Lean to medicines. Some exceptions to this included Lean applied to various drug dispensing application in hospitals (Ker et al., 2014). Similarly Hintzen et al., (2009) reported on cost savings of $289,256 with waste reduction and improvements in another hospital pharmacy. Other research searches have revealed Lean in medicine manufacture which is outside the scope of the thesis. In all these cases the criticism which was discussed in chapter 3 remains that Lean in healthcare focuses on the provider silo of the service rather than the patient. This is in contrast to the opportunity presented where there are patient value failures within the medicines. The gaps in knowledge about the outcomes of medicines in real life are not known despite the high cost and factors such as adverse genotype and clinical factors can impact significantly on success, failure, dose requirements and toxicity (Cavallari and Limdi, 2009). With medicine being a high cost area of healthcare delivery, with a large amount of known failure, there has been limited Lean intervention which leaves opportunity for the research question one to consider Lean can be adapted for long term conditions. As Lean has not analysed this area the remainder of this section will focus on key opportunities for improvement and the identification to non-value add activities and wastes.

7.6.2.1 Adherence to Medication and Reconciliation

Adherence to medication is a significant issue for healthcare with many academic publications repeating similar findings as Nieuwlaat et al., (2014) who reported that patients who self-administered medication take only about 50% of the prescribed medication. In Northern Ireland alone this means that about £0.25bn of public medication is dispensed but wasted. That cost only relates to the medication and does not put a value on the cost of managing suboptimal health outcomes as a result of not adhering to the prescribed medicines. A key controlling factor in the readmission of patients is medicines adherence (Patterson et al., 2014). A major factor in avoiding hospital readmission is to ensure the patient has all their medicines within one week of discharge (Greene, 2012). This risk of readmitting to hospital is therefore linked to reconciling the medication, ensuring the patient has the right medicines and they take the medicines as prescribed. From a Lean perspective this introduces a challenge that is not present in the car manufacturing businesses in that the consumption of the car is not linked to creating the value. If we assume that patient value is to be healthy then the adherence to medication is part of that yet the healthcare system is removed from this activity. Lean applied to long term condition must consider where the patient and the provider must co-create value. This provides some opportunity for healthcare technology as this can be deployed to support the patient and clinician.

7.6.2.2 Cost

While cardiology patients within Northern Ireland, during the period of the study, have not paid for the medicines it is recognised that pressure on the public financial system is significant. Cost is becoming a growing issue with affordability and the outcomes of medicine under increased scrutiny (Naylor and Cole, 2010). There is a need to look at new ways to find and prove value. Clinical decision makers are often unaware of cost implications between drugs of similar patient value (Time, 2013) therefore a doctor who may not have a preference between 2 drugs will randomly choose with no knowledge of the cost difference. Some of the implications of cost decisions are highlighted in the section 7.3.3 but what is clear is that decision makers are considering ways to optimise medication which includes ending the issue of medications which do not provide value and addressing wastes in the system such as overprescribing, non-adherence and the use of lower cost generic drugs where clinically safe. This is evident in the Northern Ireland "Medicines optimisation quality framework" (Department of Health, 2017).

7.6.2.3 Emerging Medication Models

There are some emerging medication models which provide opportunity for improvement. Prevention is a key topic for healthcare and the use of medication for this is an emerging trend. If a medication can reduce your cholesterol or blood pressure once you have been identified as being at high risk to prevent future intervention then medication could be considered. Yusuf et al. (2016) highlights research which used statins and cholesterol lowering drugs on healthy people as a way to reduce cardiovascular disease risk for healthy people. This research highlighted that the use of medicines to reduce risk must be balanced with the risk of creating alarm and the costs of side effects on the populations taking them. This is become a balancing of risks between prevention or screening high risk groups of individuals against negative or toxic respondents potential respondents. This could adopt the use of technology including machine learning and data mining techniques and has the potential to identify high risk patients who could benefit and also consider identifying those at risk of adverse drug reactions (Dominic et al., 2015).

Related to the risk stratification is the use of personalised medicine approaches for long term conditions as there is significant waste and non-value add in the current activities of medicine which are not targeted. Fox (2015) reported on a USA precision medicine initiative which brought together various data sources including genotyping together to personalise the medicine choices. Personalised medicine or precision medicine reflects the current failures of many drugs which will be ineffective or toxic to groups of people and uses a method of targeting the drug to only those that will respond positively (Lee et al., 2013). Personalisation addresses this by attempting to identify the individuals who will be responders, non-responders and toxic responders. This personalisation may use genetic attributes, racial characteristics, age or sex to determine if you are a responder. Personalisation could include target treatment by organ, prognostic biomarker to determine if you need treatment, predictive biomarker to determine what treatment will work and identifying those who won't respond (Van't-Veer and Bernards, 2008).

This is relevant to this thesis and Lean for a cardiology patient as some patients will be administered medicines that provide no value and some will be administered drugs which will result in a toxic impact such as causing them to bleed. Aside from errors of administering the wrong medication or wrong dosage, about 7% of hospital admissions are related to toxic drug impacts (Cavallari and Limdi, 2009). Personalised medicine to identify if the medicine will work is still immature technology and accuracy has significant technical issues which make it open to misinterpretation (Lee et al., 2013). Linked to personalised medicines is the use of companion diagnostics. The FDA "In Vitro Companion Diagnostic Devices" guidance (2014, Pg. 5) makes reference to the use of companion diagnostics as a means of "selecting appropriate therapy for a particular patient or to optimize a dosing regime". The advantage of using companion diagnostics to identify those who will benefit, remove those that are at risk of adverse reaction, monitor treatment response and identify groups of people where targeted clinical trials could be seen to be adequate for drug use approval (FDA, 2014). The main Lean healthcare point of the promise of companion diagnostics is to remove quality failure and waste in the system, however the diagnostic itself can introduce new errors as the performance of the diagnostic test may have quality issues.

In summary; the papers, qualitative analysis and grey materials reveal a significant amount of waste in the use of medication with some opportunities emerging in the technology to address a personalised approach for testing if the medication will work for you or not. The adoption of personalised medicines for long term conditions must therefore be a key part of a Lean long term condition management as outlined in research question 1 as personalised medicine reflects patient value. Without this personalised care treatment approach, care will be given that raises hope falsely or causes toxic effects. Within this one has to be mindful of the early nature of personalised medicines as scientists are only beginning to link genetics to responders or non-responders and there is some way to go before this becomes mainstream practice.

7.6.3 Analysis of Current Measures and Data within the System

In this section Northern Ireland open data sources have been used in quantitative data analysis for medicines in cardiovascular diseases. Different from previous quantitative analysis sections is that data is sourced from procurement information. Some medicines may be procured outside of the scope of this data where it has been privately acquired by a patient and this has been determined as out of scope of the data being investigated as it is a small scale and related to not controlled medicines such as over the counter tablets and herbal remedies. The source of the data is through the Business Services Organisation (BSO). The BSO is a shared service for the health service in Northern Ireland. It has responsibilities for a number of shared services in the Northern Ireland public health Service include the procurement of medicines.

Data from the BSO the "Analysis of the Prescription Cost Analysis Northern Ireland 2016" is detailed in Appendix 7 - Table 4 and reveals that cardiovascular system prescriptions (BNF Chapter 2) are the 2nd highest in terms of volume at just over 22%. In addition they are the 2nd highest cost although at a much lower percentage of just below 12%. Central nervous system (BNF Chapter 4) is the highest for both volume and cost. The top three for cost and volume are highlighted below. The total medicine cost is listed over £439 million before discount. This context of what the cardiology spend is and how medication fits within the overall medication spend is relevant to this thesis as improvement via Lean and the application of technology requires this cost context.

The analysis of a longitudinal view of the data, specifically related to cardiology, shows that over the period for 2011-16 there was significant change. There was a 9.67% growth in the volumes of cardiology related medicines which had an average year on year growth over the period of 2.09%. This growth is shown in the figure below which are based on the number of prescription items. These items are multiple per person as the chart highlights over eight million prescription items. The growth reflects previous data of more patients being treated and initially identifies a trend of growth which appears unsustainable at face value if cost and volume are matched.

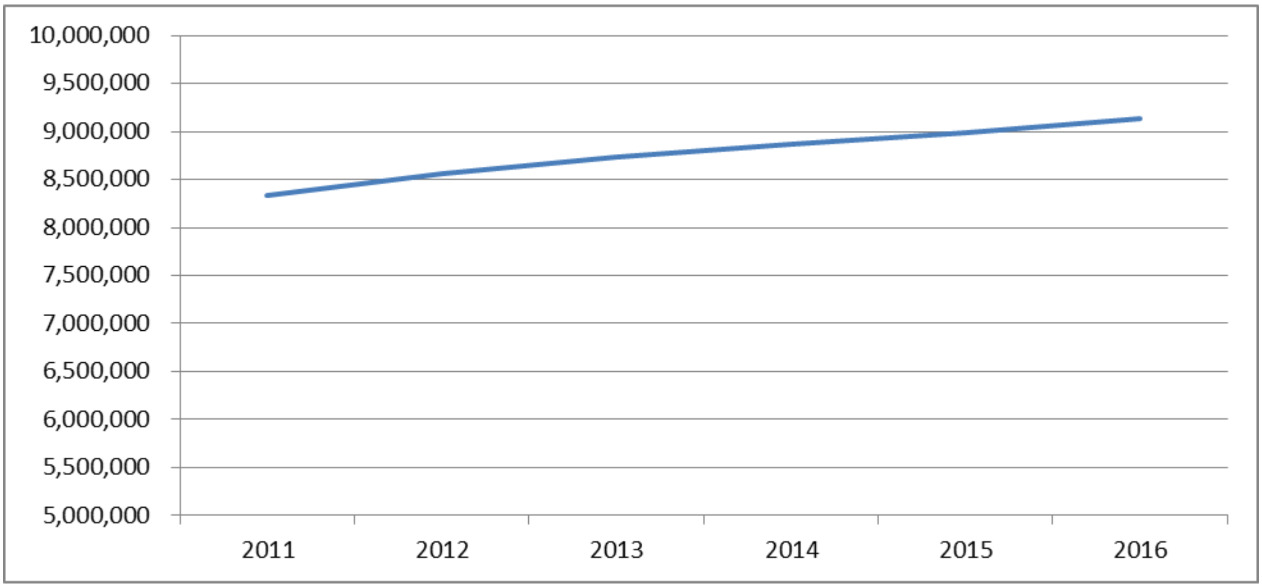


Figure 7.6.2 – Line Chart of the Number of BNF 2 (Cardiovascular system) Prescription Items (Source Data: BSO Pharmaceutical Statistics, 2018)

The cost analysis reveals a more complex picture with a 26.45% reduction in the "INGREDIENT COST (BEFORE DISCOUNT)" over the period of the analysis. This reflects £18.7m less spends between the start of the analysis and the end. The analysis reflects further complexity as far from being a constant pattern the cost increases in three of the six years. The largest increase for the period was 6.80% and the largest decrease was -17.7% which reflect significant fluctuations. The volume increases and the cost decreases highlight a complexity and the importance of data rather than assumptions. Further exploration of the breakdown of the spend is needed to create a clearer picture of the emerging changes.

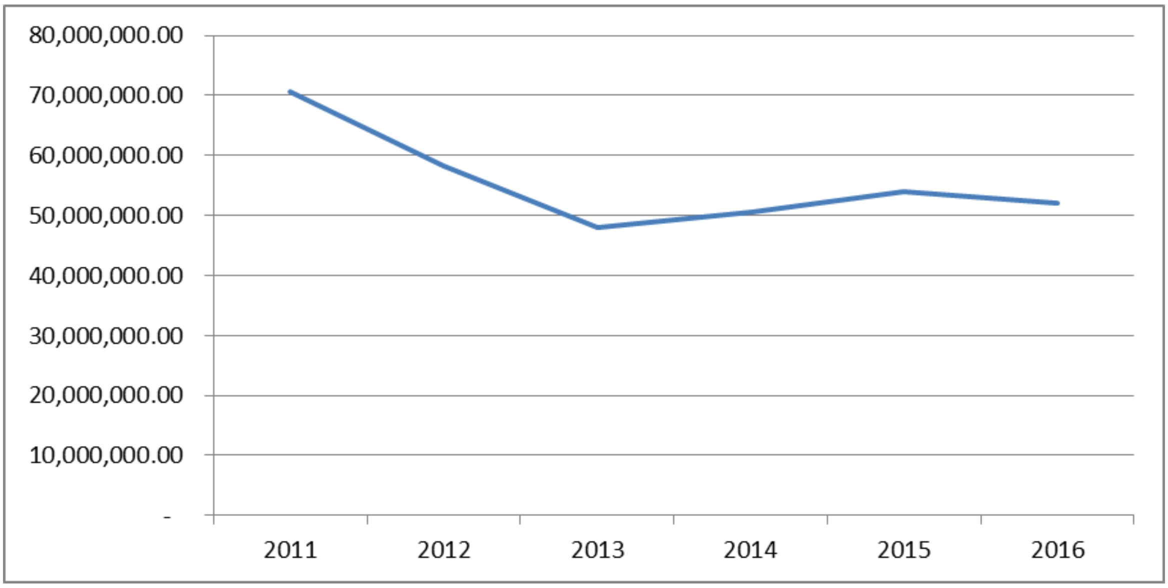


Figure 7.6.3 – Line Chart of the Ingredient Cost (Before Discount) of BNF2 (Cardiovascular system) items (Source Data: BSO Pharmaceutical Statistics, 2018)

As previously mentioned the analysis has been completed using the BNF Chapter 2. A further breakdown is available which is referred to as a "section" and this breakdown is illustrated in figure 7.6.2. "Lipid-Regulating Drugs" (Section 12) and "Drugs Affect. Renin-Angiotensin System+Other Antihypertensive" (Section 5) have the largest growing volumes. "Antiplatelet Drugs" (Section 9) and Diuretics (Section 2) both show a slight decline in volume. The analysis highlights an opportunity to utilise a Lean tool about identifying the runners, repeaters and strangers. This approach can provide some efficiency in ensuring the most common demands (Lean Term Runners) are standardised and improved from a standardised base. Repeaters then follow a common approach which is developed to become more standardised and the less common demands (Strangers) are managed with identified resources.

- **Lean Runners** - Lipid-Regulating Drugs (Section 12) and Drugs Affect. Renin-Angiotensin System + Other Antihypertensive (Section 5)
- **Lean Strangers** - Sympathomimetics Myocardial Infarction And Fibrinolysis and Local Sclerosants

- **Lean Repeaters** – All other Medicines

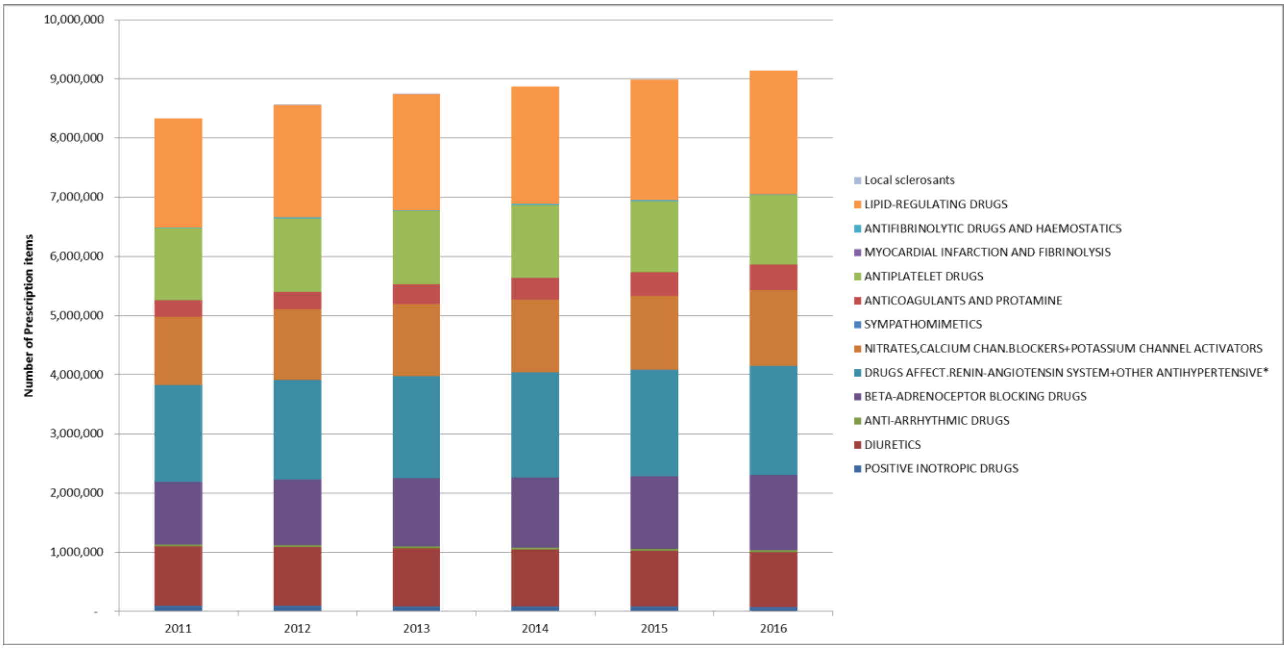


Figure 7.6.4 – Stacked Bar Chart to Highlight the Volume of Prescription Items: 2011 – 2016 (Source Data: BSO Pharmaceutical Statistics, 2018)

The earlier data highlighted that volumes alone can provide a misleading picture. The cost analysis of the chapter data reveals some dramatic new information. The overall picture was of cardiovascular disease medicines reducing significantly over the time or analysis within a period of volume growth. The cost data however paints a more detailed picture with the most dramatic change over the same time period in cost is LIPID-REGULATING DRUGS from section 12. The cost reduction during this period was approximately £22.79 million. It should be noted that the cost reduction from this one section is higher than the overall cost reduction for the whole chapter which means that other medicines are increasing in cost at the same time. The chart shows ANTICOAGULANTS AND PROTAMINE (Red) in series 8 increasing heavily over the time period. This is equivalent to an increase in cost of £11.72M with a growth rate of 71.26% volume.

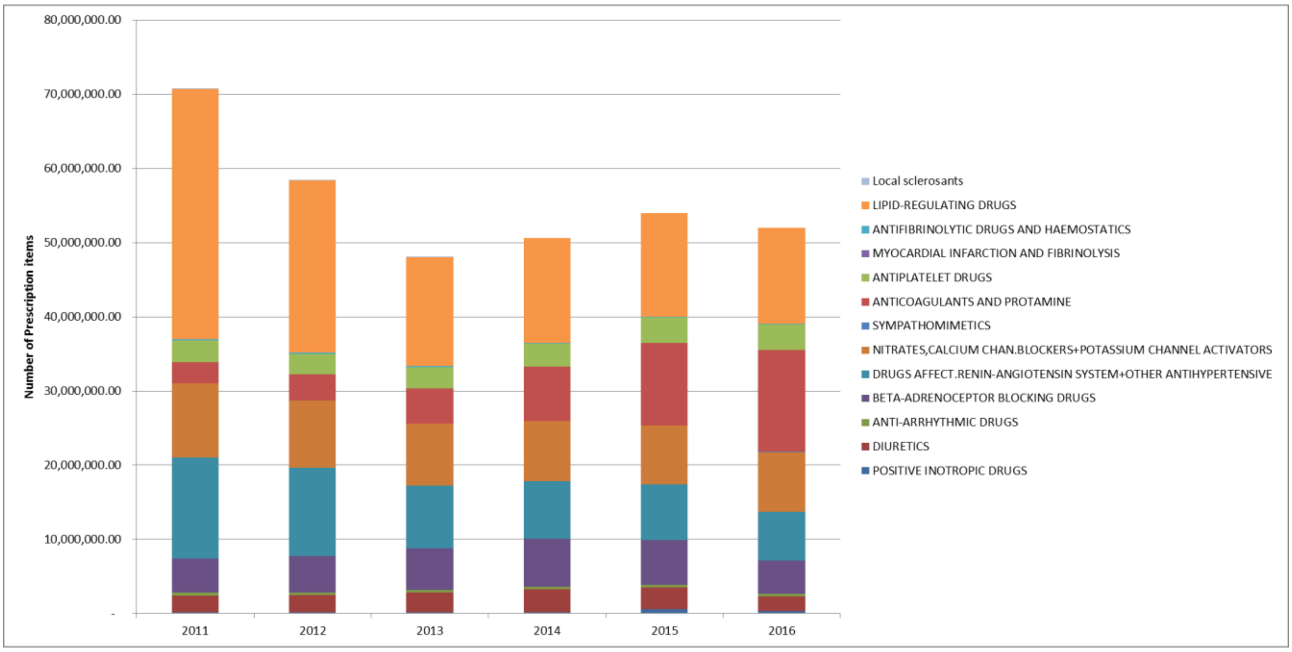


Figure 7.6.5 – Stacked Bar Chart to Highlight the Ingredient Cost (Before Discount) of Prescription Items: (2011 – 2016) (Source Data: BSO Pharmaceutical Statistics, 2018)

The above chart highlights that the following prescriptions are increasing in cost during the time period;

- Positive Inotropic Drugs
- Sympathomimetics
- Anticoagulants And Protamine

Figure 7.6.6 highlights that the following prescriptions are decreasing in cost during the time period;

- Diuretics
- Anti-Arrhythmic Drugs
- Beta-Adrenoceptor Blocking Drugs
- Drugs Affect.Renin-Angiotensin System+Other Antihypertensive
- Nitrates,Calcium Chan.Blockers+Potassium Channel Activators
- Antiplatelet Drugs

- Antifibrinolytic Drugs And Haemostatics
- Lipid-Regulating Drugs

Figure 7.6.6 reveals that the following have very low volumes

- Local Sclerosants
- Sympathomimetics

Further analysis exposes that although Sympathomimetics reflects a low volume, the volume increased by 1590% between 2015 and 2016. This reflects the changing nature of medicine discovery where new drugs go through approval to formal acceptance and roll out. This highlights the need to have a Lean continuous improvement process identifying changes in demand and supply. The analysis highlighted that Anticoagulants and Protamine are a key area of growth adding both £11.72M cost increase as well as a volume growth of over 71%.

Further data from the BSO was available in the Prescription Cost Analysis from Northern Ireland to allow the analysis to define the exact medicines within any chapter and section. A selection of this has been analysed by selecting the Anticoagulants and Protamine section data which has been presented in the below. The analysis takes a large volume of prescribing data and consolidates these into drug names which group various volumes and costs.

Consolidating the data allows a focus on this particular medicine without the distraction of volumes and methods of delivery. By focusing on the Anticoagulants and Protamine section within this analysis it reveals 23 named drugs in this category used within the HSC. Analysis of the increasing volumes reveals that just under 80% of the medicines cost is made up of three specific drugs which have been highlighted below in the Pareto analysis of all the medicines in this category.

The data itself is insufficient to make informed decisions about good practice or inform reform but this type of root cause analysis considering both volume and cost has potential for addressing patient needs better and considering the cost implications of decision making. A common approach in Lean would be the 5 Whys. For example further understanding on why it is necessary to have 23 drugs may be relevant as Lean operations have found value in reducing their available suppliers and building more strategic relationships. Table 3 in appendix 7 reveals technical details about the volumes of medicines with 3 drugs making up over 79% of the costs.

A second point emerging in the data above is that the highest volume use is warfarin yet it is only 3.93% of the total cost. Warfarin is known to be a significant risk to patients and the patient is often monitored heavily as high dosage can result in thinning the blood too much and has significant and fatal implications. The NHS website highlights that patients must follow guidance very carefully and testing;

> *"You'll have regular blood tests at your GP surgery or local anticoagulant clinic to make sure your dose is correct." – (NHS Choices, 2016)*

The Lean challenge is that the warfarin represents a low cost solution used by a large volume of patients. The cost however is not a full cost as the patient must attend various clinics to test blood regularly. The NHS website however reveals that rivaroxaban, apixaban and dabigatran are alternative emerging solutions that do not require the monitoring clinics.

In a simulation scenario for this thesis, where the same volume of warfarin was replaced by Rivaroxaban this would increase the cost for medicines in this category from £13.7M increases to £42.3M. While this is a high level calculation which would be refined with bulk purchases and other factors may mean that the volume is not a 1:1 replacement. The concept of hidden costs in the value stream is an important factor for Lean reform considering long term conditions. The cost of the failure of warfarin in terms of death and monitoring of patients is difficult to quantify yet the scenarios of new medicines reveals significant cost hikes that may be beyond the reach of a struggling health budget at face value.

7.6.3.1 What Data is Not Captured?

Linkage between the medicine and other health data such as readmissions and hospital admissions would be useful analysis to understand if medication is leading to lower costs elsewhere in the system. Opportunities are lost as the activity of the rest of the treatment is not available which means that one can't triangulate with the implication of bed days or other costs. The full cost of a medicine is not available as the cost of supporting activities such as clinics to monitor the INR measurements of patients are not provided.

Relationship between medications is not explored as patients with co-morbidities require multiple medications which may conflict leading to poor value. This was revealed in qualitative analysis where patients approaching end of life were removed from medication to then significantly improve revealing the medication causing part of the condition rather than being a value add. Linked to this are medicines adherence issues and the link to the good practice of discharging clinicians. Patterson et al. (2010) highlights that prescribing of data blockers at discharge resulted in lower mortality rates but this assumes the patient is taking the medication as prescribed. Adherence is not measured routinely and technology does not provide an adequate solution to address adherence effectively.

The outcomes of medication are not measured and this is one of the largest failures in the value stream in the current provision. The business case analysis of precision medicine is based on the fact that some drugs don't work on some people but in practice it is not known who they don't work on. For this reason the outcomes of real world use of medicines is largely not known.

7.6.4 Lean Wastes/ Lean Non Value-Add Activities

This section explores Lean failures in healthcare identified from the literature review in Chapter 3 in applied to medicines for cardiovascular disease patients.

Table 7.6.1 **– Literature Review Lean Waste Categories Aligned with Cardiovascular Disease: Medicine Focus**

Healthcare Failure Area Identified in Chapter 3	***Evidence in Cardiology***
Waiting times	Literature reference to drugs not being available at discharge resulting in readmissions for heart failure patients.
Delays	Delays in identifying decline in patients' health due to titration of medication after discharge results in patient readmitting in heart failure.
Diagnostic	Companion diagnostics provides opportunities to diagnose the impact of the medication. This is largely not done today therefore there is a waste associated to lack of diagnostics.
Medical Complexity	Drugs issues (BMA concise guide to medicines and Drugs fourth edition 2012) • Oxygen supply in blood • Flushing headaches • Dizziness fainting • Dangerously Lower blood pressure • Swelling • Kidney issues • Blood levels rise in acids • Risk of Gout • Blood sugar levels risk to diabetes • Overactive Thyroid Related diseases/symptom (BMA concise guide to medicines and Drugs fourth edition 2012) • Hypertension • Blood pressure • Angina • Stroke • Kidney illness

	• Breathlessness due to excess fluids related to drugs not working to remove fluids.
Additional Healthcare Visits	Incorrect or ineffective medicines leading to additional appointments with doctor.
Co-ordination of Healthcare resources	Impact of medicines leading to co-morbidities issues not addressed.
Length of Stay	Ineffective use of prescribing in early stages will result in longer lengths of stay.
Cost	• High cost of drugs • Hidden costs of having to monitor biomarkers for specific medications that can be dangerous, addictive or have negative side effects. • Overprescribing (significant discussion in qualitative analysis – medicines focus group).
Quality	• Providing drugs or treatments to non-responders of medicines. This is not known at time of prescribing and will not be an error but does reflect overall quality. • Medication leading to poor health outcomes – toxicity. This is not known at time of prescribing and will not be an error but does reflect overall quality. • Staff turnover within the care sector reflects lower knowledge transfer and skills for medication. This is relevant as many patients care sector will have cardiology related conditions many medicines. (Discussion in qualitative analysis – medicines focus group).
Emergency Admissions	Significant numbers of emergency admissions are linked to medication issues. (discussion in qualitative analysis – medicines focus group).
Death	Medications can result in a threat to life with warfarin and blood thinning medications of particularly high risk.
Medication errors	• Wrong drugs or dosage prescribed based on not following guidance.

	• Drugs selection not considering other health conditions such as diabetes, asthma or kidney issues. (co-morbidity).
Infections	Antimicrobial resistance is an issue in drug prescribing policy. This is linked to not having the right drugs to address an infection (Significant discussion in qualitative analysis – medicines focus group).
Emerging from this research and not covered in Lean Healthcare Literature	Service provision often fails to address client choices of individuals who may want to trade-off longevity or symptoms against quality of life aspirations. E.g. tolerate pain but avoid side-effects of medications which prevent family engagement. • Limited use of technology to complement service delivery • Limited use of data to inform the care needs – no single view of medications prescribed today. (discussion in qualitative analysis – medicines focus group). • Examples of medicines technology have struggled to define route to adoption

7.6.5 Discussion on Medication

Medication has a high failure rate which is not fully understood by the patient and is accepted by the medical establishment due to being perceived as doing more good than harm across patient groups. Within the medical establishment however while there is acceptance that in approving a drug a calculation has been made that side effects will be evident for some groups but what is not understood is the actual outcome for all patients. This is not measured beyond returning patients with side effects or lack of progress where at that stage the doctor may change to an alternative drug.

Lean and technology have opportunities to start to measure those outcomes over longer periods in real time outside of the clinical trial. Emerging technology in the form of personalised medicines and companion diagnostics also has some opportunities to begin to address the waste through identifying toxic and non-responders with more accuracy using genetics and other factors. In addition technology has options of providing prompts and advice to prescribers who are about to prescribe drugs that conflict with other conditions. Technology can support drugs reconciliation against best guidance and presenting conditions to provide options to address the waste of bad prescribing patterns and provide clinical decision support for doctors. In these points research question 2 is starting to be addressed as technology can identify the Lean wastes and begin to address these.

The data analysis also reveals some significant changes in costs that have the potential to be unsustainable in a budget constrained health service. Lean healthcare technology could assist in modelling and making decisions around this as full patient focused value streams could assist in keeping focus on patient value rather than additional cost drivers.

Finally, the engagement with the patient is a significant gap not explored in Lean healthcare and has significant impact on long term conditions. This comes in two places with the first being related to adherence to medication and the second being in decisions about treatments that create value for a patient. The medication adherence is a complex area with many issues about why medication is not taken. Some of it may be related to forgetfulness, bad advice, side effects, public news on the specific medication and a belief that they don’t need it anymore. Within this is a mixture of fact and perceptions and Lean has a potential to understand the root cause in order to identify steps forward. A specific Lean tool around the 5 whys is an option with patient groups. The second point about decisions around treatment is again a complex issue as a patient may make a perfectly logical decision to not be treated or not take medication. A patient may feel that further surgery or intervention is not welcome and palliative care to manage their condition may be more attractive for them and their family. Similarly medicines to thin the blood which are risk reducers may result in dizziness or lack of confidence that is unwelcome to a patient and they may prefer the higher risk with less daily side effects. In both cases patient value is emerging which may not be the medical professions first choice but in long term conditions identifying value for the patient will be paramount. In this point research question 3 is beginning to be addressed as health technology and data can begin to redefine patient value. This can also assist in answering research questions 1 as Lean can be adapted for long term conditions.

7.7 Healthcare Technology

The previous section of the thesis analysed medicines for cardiovascular disease patients in the care pathway. In this section the thesis moves away from activities within the value stream to supporting technology. In figure 7.2.1 and replicated within figure 7.7.1 below one can see healthcare technology is the final focus area to be analysed. In chapter 4 of this thesis the use of technology within healthcare revealed opportunities to address patient value and the absence of technology within Lean healthcare publications. This section will assist in addressing research question 2 about if healthcare technology can assist in identifying and addressing Lean non-value activities. In addition research question 3 can be addressed by considering of healthcare technology from data focused technology can assist in redefining patient value. The focus will be on the use of technology in cardiovascular disease to avoid replicating any findings from chapter 4.

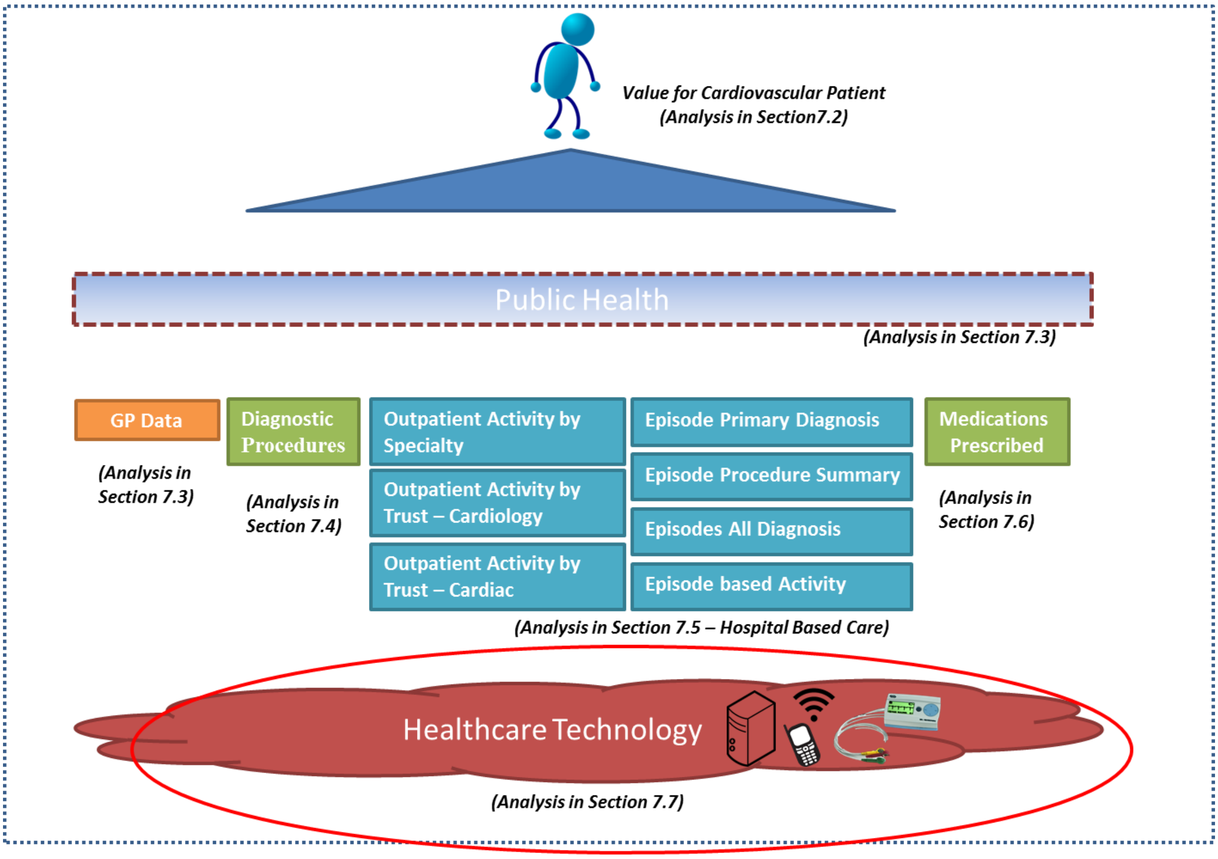


Figure 7.7.1 – Cardiovascular Disease Data Set – Focus on Healthcare Technology

7.7.1.1 Technology Definition in Cardiovascular Disease

The NHS strategic document “Five Years Forward View” (NHS, 2014) is the current strategy documents for technology in the NHS. In the foreword it states that we should “take advantage of the opportunities that science and technology offer”. It also refers to technology giving us the ability to “predict, diagnose and treat”. The World Health Organisation defines healthcare technology as “the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives” (WHO, 2016). Within these two different organisations one can see healthcare technology definitions can be specific to care intervention or wider impact on the organisation of care and supporting a patient. For the purposes of this thesis the definition will cover specific care provision and the organisation of care. This wide definition is necessary as the research questions asks about non-value add activities, dealing with long term conditions and patient value which is inclusive of specific care intervention and system to assist in organising healthcare delivery.

7.7.1.2 The Role of Technology

Technology, systems and digital provide a role in organising care which can be within a specific clinical group or across clinical boundaries and promoting the sharing of information between professionals (NHS, 2014). The technology can also be suitable for clinical purposes such as scanners and determining DNA types. Beyond the organising of care and clinical utility there was also a role for technology to engage patients through managing their data, accessing information and sharing data with clinicians. Finally there is an operational use in maintaining standards and increasing productivity and efficiency.

7.7.1.3 Future Development of Technology

The future technology in health emerges from a sense of previous failures and the National Advisory Group on Health Information Technology in England (Wachter, 2016, Section 4) said "overly centralised decision-making, combined with a lack of local engagement, meant that users' needs were poorly understood and providers were directed to implement at pace systems they had little say over". The failures recognises two extremes which have both not worked which is a highly centralised approach linked to the NHS England "Connecting for Health" programme resulting in no local ownership and 'letting a thousand flowers bloom' which meant that there was thousands of different systems and standards (NHS, 2014).

Enabling and enhancing care which is out of hospital, supporting community based care and integrating systems appear to be the key directions which support an ageing population and by default the cardiology patient. While these aspirations make some degree of sense they do also mention a need for more evidence of the effectiveness to support the use of technology. Within this lies a number of tensions for technology which are that technology is disruptive and clinical evidence is slow at best and often inconclusive. Additionally technology can cost money for cash constrained organisations (Currie and Finnegan, 2011).

7.7.1.4 Technology Analysis in This Thesis

With the definition, role and future direction explained, the remainder of section 7.7 will adopt a similar approach of use in the previous sections 7.3 through to 7.6 by analysing;

- Current role for healthcare technology in academic and grey papers
- Emerging measures and data healthcare systems
- What is not measured?

- Cardiovascular disease healthcare technology against the Lean non-value adds activities identified in academic literature in chapters 2-4.

What will be different from previous sections however is that this will not focus on specific patient data but on information about the use of technology at the various stages of the cardiovascular disease value stream. The section on the current role for healthcare technology will look at the current use of technology across the value stream and the mapping of technology onto the sections of the patient value stream that have been explored in section 7.3-7.6. The emerging measures and data section for technology is a modification from earlier chapters as instead of looking at the patient data it will look at data to suggest emerging technologies that may be of relevance. In previous chapters this was limited to Northern Ireland but to be relevant to the research questions this will be expanded beyond Northern Ireland to technology searches of emerging technology of relevance to Northern Ireland cardiovascular disease care provision. Again the emerging technologies will be mapped against value stream activities explored in sections 7.3 – 7.6.

From this analysis one can then contribute to answering the research question 2 about if healthcare technology can assist in identifying and addressing Lean non-value activities and research question 3 about addressing if healthcare technology from data focused technology can assist in redefining patient value. Figure 7.7.1 illustrates the source of data used to build a complete view of the health technology landscape for cardiology within this section.

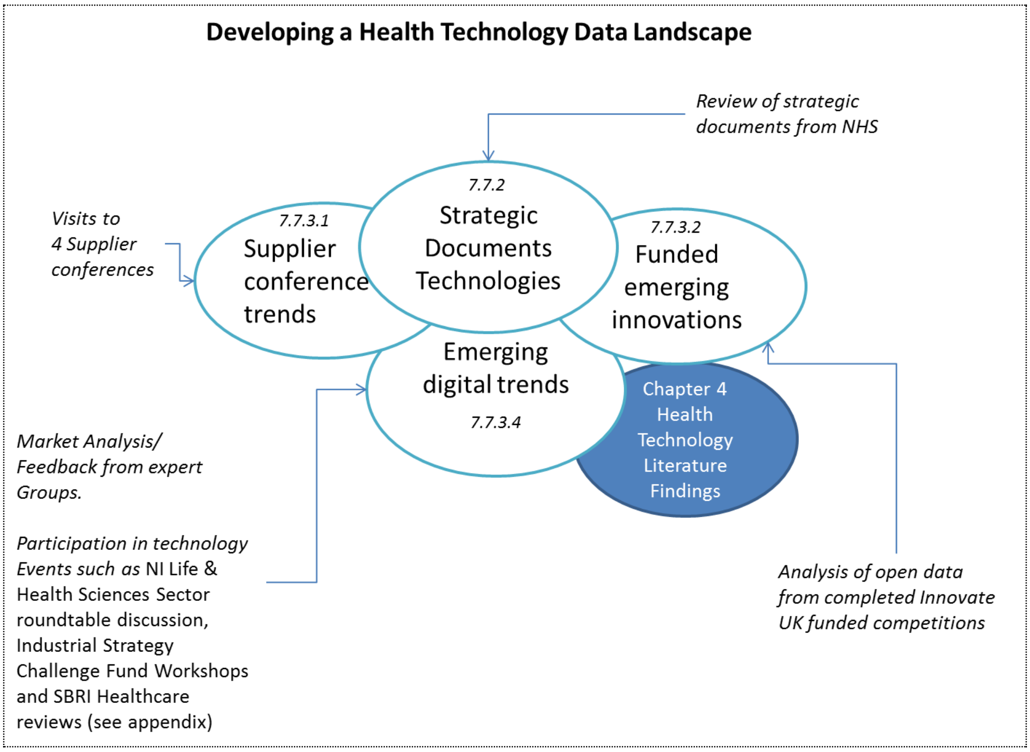


Figure 7.7.2 – Developing a Health Technology Data Landscape

7.7.2 Analysis of Cardiovascular Disease Technology through Papers and Grey Materials

This section considers the technology application related to cardiovascular disease. This analysis will focus on the current use of technology either in current healthcare practice, in papers or identified in grey papers. The analysis will utilise the chapter topics along the values stream as identified in section 7.3-7.6 which are;

- Prevention, primary care, community care and personal health
- Diagnostics
- Hospital based care
- Medicines

By linking together the value stream activities with the use of technology in this section it is possible to identify the gaps or where technology has a lower level of maturity in care provision. In figure *7.7.2* technology has been identified from a number of strategic documents and mapped against the thesis section headings which represent the cardiovascular patient journey. What becomes clear in doing this is that although there are strategic intentions to include certain aspects of technology there are gaps. What is learned from this is that many of the items of current provision are relevant to patient value however there are large gaps in the provision of that technology. In particular these unmet needs related to what is happening outside of the hospital and are blind spots to the clinicians and decision makers. The clinician can for example see what is happening to the patient within their care but they are unable to have any real-time feedback on response to therapy outside of the hospital (Sharon, 2017). In addition the area of prevention is a large gap. Technology has had some impact on prevention strategies with mobile health addressing diet, education, risk reduction, surveillance and disease screening. Franklin et al. (2015) paper on "Personal health technology: A new era in cardiovascular disease prevention" highlights that ICT offers "affordable, approachable and accessible" mediums for delivering healthcare for Cardiovascular disease. A key phrase appearing in the paper is behaviour change which is reflected in strategies but is often seen as a missing ingredient in the outcomes of public health prevention strategies.

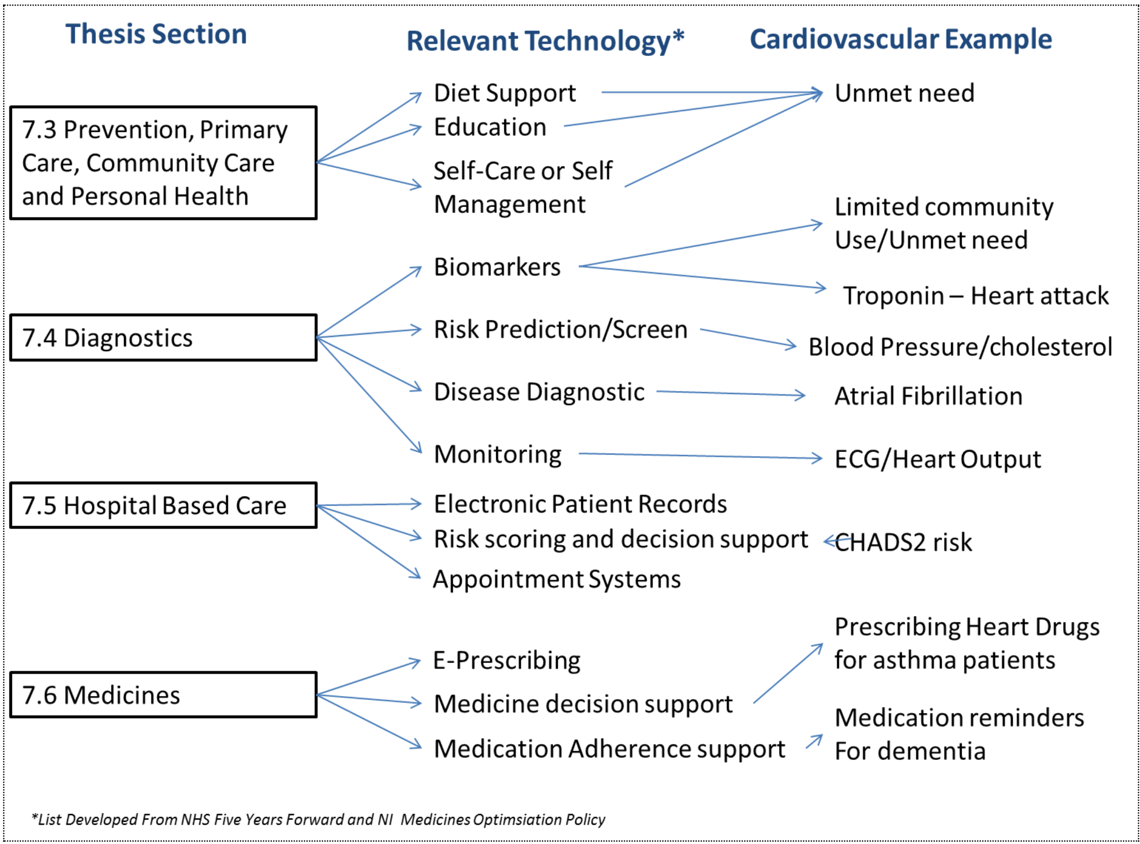


Figure 7.7.3 –Technology of Use Case for Cardiovascular Disease

7.7.3 Analysis of Current Measures and Data within the System

Technology is evolving at a rate that makes it difficult to utilise academic or current practice publications alone as a good barometer of the future adoption. Exploring technology identified in emerging technology conferences and other areas outlined in 7.7.2 may address some of these gaps. To address this, an analysis of emerging technologies from suppliers and other providers will be used. This section does this by analysing;

- Supplier conference trends
- Funded emerging innovations
- Emerging digital trends

This analysis will continue to be focused on cardiovascular disease as an example of a long term condition and the research questions 2 and 3 where addressing non-value and utilising technology to assist in redefining patient value in important.

7.7.3.1 Emerging Supplier Commercial Offerings

Trends in commercial and healthcare focused conferences can provide insight as they reflect emerging products from suppliers. Many of the conferences provide supply side technologists a platform for interested parties to see their solutions. The four following conference represent a mix of European and International conferences with relevance to cardiovascular disease.

Table 7.7.1 –Sample of Health Tech Conference in 2016

Conference	**Medica, Dusseldorf – Nov 2016**	**EHI Birmingham 2016**	**WISH, Qatar 2016 -**	**Connected Health Symposium, Boston 2016**
Focus	*Current Providers with Wide Health Technology Application (Largest in Europe)*	*Current providers targeting Digital healthcare (Largest E Health conference in UK)*	Global Health provider focus, *Invite only and generally only futuristic innovators demonstrating.*	*Mix of Innovators and Current Providers.*
Key Topics Covered By Demonstrations	Electromedical equipment and Medical Technology	PAC (Picture Archive and Communication) Digital	Genomics Data Patient	Data Devices System

	Laboratory Equipment Diagnostics Physiotherapy and Orthopaedics Commodity and Consumer Goods Information and Communication Technology Medial Service and Publications	Architecture Business Management Informatics Information and Communication Technology Electronic Patient Record System Integrators	Behaviour Drug Resistance/ Infectious Diseases Novel Technologies – Such as Ingestible sensors, Augmented and Virtual Reality Chronic Condition Management	Integrators Patient Behaviour – Apps and Engagement Tools

In summarising the supplier's interests one finds a number of common areas emerging across the various industrial conferences;

- Laboratory Equipment
- Medical Devices - Including Diagnostic Devices
- Digital Tools
- Electronic Health Records
- Communication
- Informatics
- Healthcare Apps
- Consumer Wellness and Health Technology

Similar to the previous section from the healthcare providers; laboratory equipment and medical devices form a key part of technology related to cardiovascular disease. When exploring from the supplier side there are clearer product related to the integration of technologies that are not specific to cardiovascular disease but are needed to link systems and administer patients. These can be absent from strategy and related documents as they reflect back office systems which are needed but aren't somewhat unattractive for a strategy document.

In private healthcare markets such as the USA and the Republic Ireland, the linking of data is not as mature as the UK and forms a bigger part of the demand from healthcare provider's aspirations. The American strategies refer to the Hi-tech Act which outlined an electronic health record strategy with various incentives and penalties. Informatics plays a larger role in the supplier conversations but is present in both.

The use of data is seen as core to the future for all localities but this has some caveats around the sharing of data. "Care.Data" is an example of a UK government initiative which was largely rejected by the public due to fears over security and decision making. This is in contrast to progress in other parts where the sharing of data has occurred without the same levels of controversy. The use of apps and consumer focused technology has however been sporadic and lacks high levels of adoption. In this area we see a mismatch between supply side and the demand from providers.

Diagnostic equipment has largely been an accepted part of healthcare for some time now. The equipment has gone through a slow evolution with the identification of various bio markers being a constant theme. The number of biomarkers in clinical practice or how they are used has not undergone significant change despite the discovery of new biomarkers. In cardiovascular disease there are a small number of recognised and agreed on biomarkers which are used. The introduction of novel measurements can be slow and difficult to drive mainstream adoption. This point emerged in qualitative analysis with the cardiology focus group where it emerged there were very few accepted new biomarker of shared value among the cardiologists. Point of care diagnostics to take the “lab” closer to the patient is of interest but this again does not have widespread adoption at this stage.

Medical devices have been in used as a technology for some time and form a large part of today’s healthcare pathways in cardiovascular disease. Diagnostic procedure to measure the heart in various states is a core of the decision making.

One can also see that technology is already in use for risk scoring systems, decision supports and automated ECG interpretation attempt to assist in managing the complexity presented and the tools aim to reduce the risk of inappropriate discharge as part of a clinical assessment.

7.7.3.2 Emerging Innovators (Funded by Innovate UK)

Innovate UK fund the technology industry (mainly SME’s) for emerging projects. Data on summaries of these projects is available in an open data format for projects since 2004 (Innovate UK, 2017). The data from this is useful to identify potential emerging products and interests from a technology push perspective. For this analysis 2011- 2016 has been focused on and the terms cardiology, cardiac, cardiovascular and heart failure have been used as key search criteria. An analysis of each of these technologies was completed to link the technology to Lean failure potentials and a summary of the learning is available from the analysis in appendix 7, table 5.

The analysis of the emerging technology from Innovate UK reveals number of interesting overlaps with previous Lean cardiology studies from 7.2 – 7.6.

- The lean failures of medicines, diagnostics, infections, decision are overlapping with the technology push from the Innovate UK technology projects.
- Training is an area that has not emerged on the Lean side of the analysis but appears in the Innovate UK technology projects.
- Implantable devices which are relevant to cardiac surgery are covered in this list but not identified in the Lean discussions as clearly due to the focus on higher level flow of patients.

7.7.3.3 Emerging Digital Trends

Beyond the specific Innovate UK technology projects one can see a number of emerging digital trends in analysis and throughout the qualitative discussions. These include interest in social media, IOT, data analytics, machine learning and virtual reality.

The use of social media is not widely explored in the patient journey or patient value. This seems counter intuitive as patients are using mobile phones and search engines frequently as a symptom checker. To illustrate its potential a number of the key medicines for cardiovascular disease identified in 7.6.3 which were showing growth in volumes and costs included warfarin, Rivaroxaban, Apixaban, Enoxaparin were analysed on social media. The following google data analysis was then completed to illustrate google trend analysis and its potential contribution (Google, 2017).

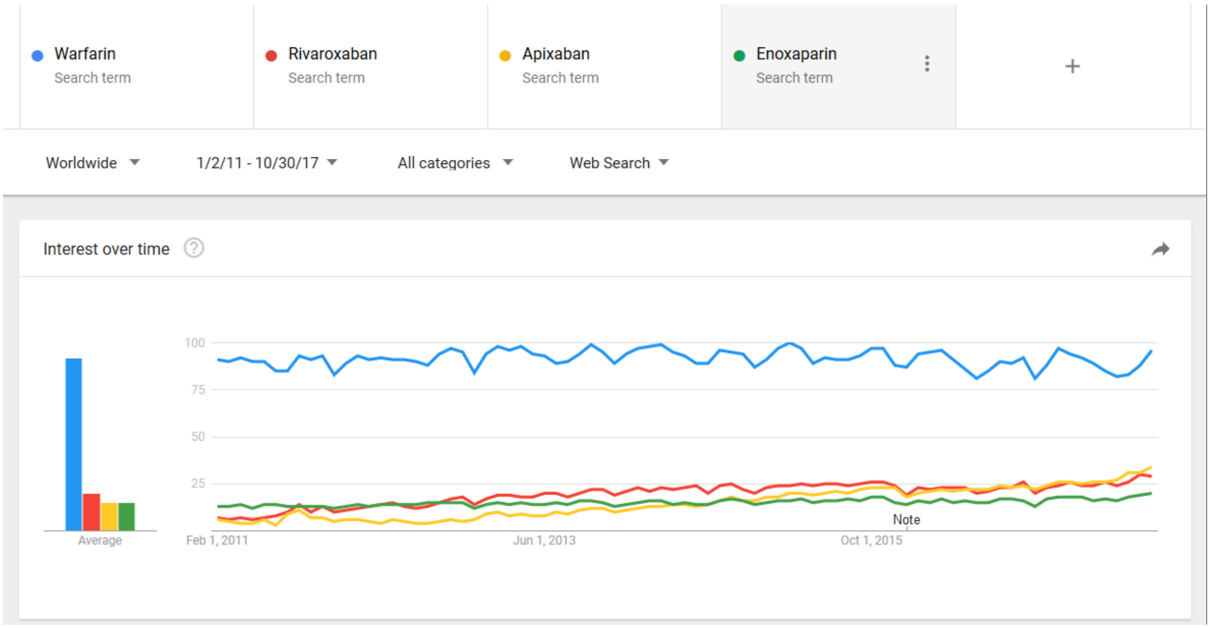


Figure 7.7.4 - Google Trends for Warfarin, Rivaroxaban, Apixaban, Enoxaparin 2011-2017 (Source: Google, 2017)

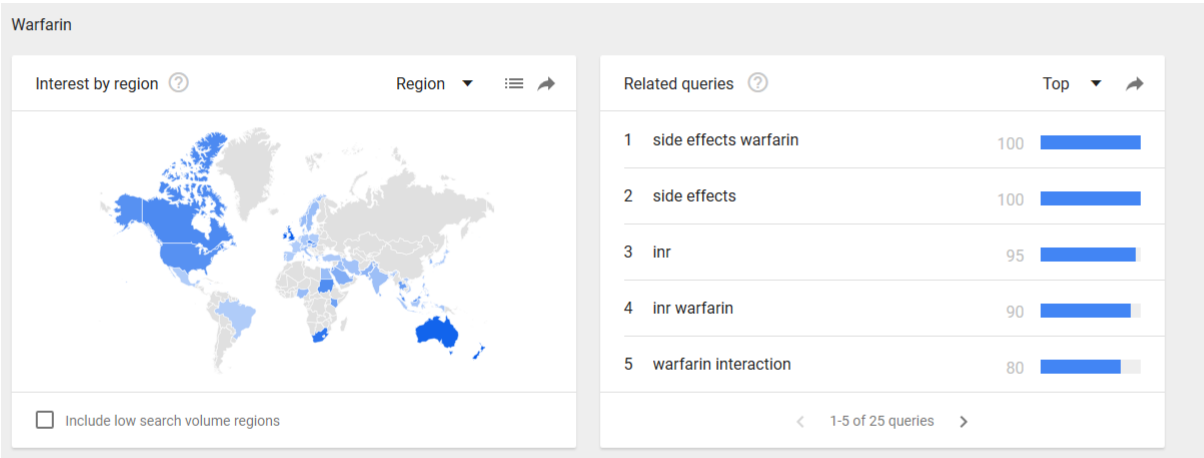


Figure 7.7.5 Google Related Queries for Warfarin, Rivaroxaban, Apixaban, Enoxaparin 2011-2017 (Source: Google, 2017)

What is clear is that the high volume of google search interest reflected in the trend data is related to warfarin however one can see that over the 5 years the other three medicines are growing in their relevance. With this analysis, it starts to build the frequently asked questions related to Warfarin which may be an appropriate route for personalised education. The analysis highlights the ability to look at geographic localities and there are opportunities to narrow down to regions and localities and create a more dynamic p personalisation. The use of digital and social media data may therefore be useful in understanding patient behaviours, patient queries and potential emerging patterns of non-adherence to specific drugs or treatments. The use of social media data in healthcare is not without issue as flu surveillance used social media data from over 50 million search terms data. This however predicted more than double the proportion of doctor visits for influenza like illness than the Centre for Disease Control and prevention (CDC) which bases its estimates on laboratory reports (Lazer et al., 2014). Additional issues are raised around the widespread adoption of social media due to changing algorithms by providers and influence of manipulation from commercial organisations with marketing campaigns.

Augmented reality has found some use cases for healthcare education due to the cost and resource intensive nature of medical training although this was mainly linked to early explorations and lacked scale or widespread adoption (Zhu et al., 2014). Remote healthcare also made some attempt to utilise augmented reality with the focus on bring better healthcare to remote locations (Heyes et al., 2017). In addition, the WISH conference referred to in the market analysis had an example of augmented reality supporting remote supervision of hand surgery. In summary the area has some potential but it us very early stages to create valuable and scalable products.

The use of analytics and machine learning has a lot of potential for learning behaviours and relationships which are not fully understood by clinicians today. A significant amount of literature is emerging on the topics of big data, machine learning and artificial intelligence in healthcare which is beyond the scope of this thesis. Within the thesis scope a number of explorations are being completed with the use of machine learning in cardiovascular disease utilising clinical knowledge to identify classifiers which could then make sense of the data gathered from clinical disease datasets. These explorations see potential in bypassing clinical trials, reducing admissions, finding adverse drug reactions, reducing hospital acquired infections and reducing fraud by using data analytics (Dominic et al., 2015)

The Internet of Things (IOT) is a term that is frequently on the market strategy documents of many technology organisations. Emerging behind the IOT devices are novel networks which have the ability to communicate over a long range with low levels of power. At its simplest level, the technology provides a means of inexpensive secure long distance communication between a sensor based in the community and the owner of the sensor. Examples include LoRa and Sigfox. The communication requires very little power so a sensor may have a battery attached which is sufficient for the life of a device. The sensor could be measuring, temperature, location, movement, air quality or many other pieces of data. The data can be passed back to a server and presented to a decision maker with other similar pieces of data. Businesses are exploring new solutions with this inexpensive data collection to monitor tourism, improve agriculture, streamline health service delivery, improve service delivery and drive up operational efficiency. This is the Internet of Things, but many of the business applications are still to be discovered. Specifically for cardiovascular disease there are opportunities linked to smart cities about health promotion which has a direct impact on non-communicable diseases such as cardiovascular disease due to the promotion of healthy activities which reduce risk factors. This has been evident in Belfast City Council Smart Belfast initiative where health is one of five challenges for a smart city (Belfast City Council, 2017).

Other trends such as wearables have some interest but recognition that 60-70% variability between devices is not appropriate for clinical grade data. GI Medicine is also technology that allows for a smart camera and smart pills but these are at an early stage. Wearable tattoo with vital signs again have also some futuristic opportunity when refined and applied to the clinical challenges in a robust manner.

7.7.4 Lean Wastes/ Lean Non Value-Add Activities

This section explores Lean failures in healthcare identified from the literature review in Chapter 3 in technology for cardiology patients.

Table 7.7.2 **– Literature Review Lean Waste Categories Aligned with Cardiovascular Disease: Technology Focus**

Healthcare Failure Area Identified in Chapter 3	***Evidence in Cardiology***
Waiting times	• Technology to reduce reporting waiting time of diagnostics tests. • Long waiting time for technology such as MRI scans, ECG testing, and
Delays	• E-referral to remove delays • Information exchange via electronic health care records
Activity Transaction Speed	• Point of care testing can remove delays in diagnostic information therefore accelerating the decision time for beginning treatment.
Diagnostic	• Technology available to provide rapid diagnostics to remove waiting delays. • Technology can create wastes in false positives and false negatives which can lead to unnecessary investigations or treatment.
Medical Complexity	Technology can assist in clinical decision support for complex decisions requiring insight from different clinical specialties.
Additional Healthcare Visits	Patient groups can receive activities which do not add value to them as individuals - medicines for example improve patient groups, not individuals.
Co-ordination of	• Shared care records, activity lists, shared notes, shared

Healthcare resources	medication record, shared allergy information all contribute to the coordination of staff. • Updating of electronic records can add additional activities to a busy healthcare worker compared to ticking a box on a paper based system. Issues identified in technology implementation of additional time requirement and also loosing patient/clinician contact time while clinician updating records.
Length of Stay	High ALOS related to heart failure patients. Opportunity to consider alternative models which have been successful in maintaining quality outside of hospital.
Quality	• Biomarker related technology to focus intervention to specific needs. • Innovate UK (2017) new products emerging identified various clinical measures that were not of a high enough accuracy – such as cardiac output measurements. • Diagnostic technology depends on high sensitivity (identify those with the disease) and specificity (identify those without the disease) or waste and failure will be created. • Stents and pacemakers both address quality issues but procedures can then create quality failures such as clotting, incorrect procedures or responses from specific patient groups.
Medication errors	• Companion diagnostics can identify the patients who will p respond to medication and non-responders to remove errors. (Lee et al., 2013) • Medication compliance technology in its infancy with IOT/smart homes technology providing some options around reminders.
Infections	• Use of technology may be a source of some infectious disease spread as machines and technology are passed between professionals (Design consideration and cleansing processes needed). • Data analytics and machine learning can identify patterns of

	infection, staff behaviors in a hospital that may have led to infection spread, patterns of drug dispensing that would encourage drug resistance leading to infections and data relationships to environmental factors. • Technology can be used to keep people away from infectious disease areas but still gain access to professional clinical advice remotely.
Emerging from this research and not covered in Lean Healthcare Literature	• Promotion of wellness, education and engagement with patients to address poor behaviours about their condition. Missed in Lean healthcare as focus is on activity. Emerging opportunities in augmented reality and virtual reality to encourage better engagement in education. • Social media provides insight to the “patients” queries and issues that will need addressed yet this is not actioned or acted upon. As demonstrated with warfarin in the previous section. • Diet and exercise related technology missed in Lean healthcare as method of addressing risk factors for patients. High impact due to obesity leading to most non-communicable diseases. • Emergent models such as telehealth, telecare, hospital at home missed by Lean healthcare approaches. • Self-care and self-management. With technology help. • Overload of data from technology can result in further confusion. • Waste opportunities in the patient information due to not aligning data leading. • Technology which does not consider the use within a working hospital may result in too many alarms which are known as alarm fatigue by staff. • Risk scores to identify patients at higher or lower risk can be dynamically supported by technology – for example e.g. – “CHADS2” risk stratification scoring is used in

	cardiology as a measure of risk for specific heart rhythms or stroke. (Svendsen et al, 2013) • Waste opportunities in the patient information due to not utilising data to inform when to begin end of life or palliative care planning and change in emphasis of care.

7.7.5 Discussion on Technology

By applying technology to the activities in cardiovascular disease in sections 7.3 – 7.6 it is possible to identify contributions to research questions 2 & 3 as technology a number of technologies have been identified that can assist in identifying Lean non-value add activities and assist in redefining patient value. The analysis shows that prevention, primary care, community care and personal health have a lack of technology embraced in targeting exercise, wellness and community based use cases that could prevent cardiovascular disease. Prevention of the disease would address significant portions of the World Health Organisation (2015) reports “Action Plan for the Global Strategy for the Prevention and Control of Non communicable Disease”. Technology provides opportunities address the missing links in public health between activities and outcomes. Data related technologies and in particular big data, deep learning or machine learning also has potential to address poor patient adherence to guidance and medication through personalising interventions. Through machine learning an algorithm may be able to provide relevant prompts or reminders which are targeted at an individual’s needs. Some mixed results on the use of data to date should however provide some caution about overfitting data (Lazer et al, 2014).

The clinical and business case evidence for adoption of new technology in care provision in the hospital, diagnostics and in the community can be a significant issue which emerges in many of the qualitative focus groups. Evidence of effectiveness and efficiency are required to gain technology adoption for new solutions. This can be fraught with issues as the adoption must look at the clinical evidence, business case and adjustments to the care pathway which collectively create a significant barrier to introducing new technology. The cost of equipment leads to a need to justify sufficient return on investment which can be difficult to attain. They require the technology provider or assessor to put numerical or financial values on a life or quality in a life which can be challenging. Separate from medical effectiveness is operational effectiveness which is increasingly addressed with technology and has been free of the need for clinical trials to benefit even though there is a clinical benefit available from their use. For example a device which makes recommendations on the amount of medication will require a clinical trial and various assessments however an electronic health record that accelerates the speed of passing information to the clinician will not require a clinical trial. There are however grey areas where the data collection leads to selection of what data to present, advice related to the data and the boundaries between presenting data and providing clinical guidance. The result of both of these types of technology can be measureable in patient outcomes and the EHR may even have a large clinical utility as faster decision making as a result of having the right information, sharing of data within clinicians and more immediate access to clinical diagnostic information can alter care significantly. In addition some of the non-clinical systems which capture operational procedure, diagnosis, and prescribing patterns can reveal evidence of poor practice and non-adherence to best guidance which have been somewhat hidden in paper based systems.

The debate on quantifying the benefit of technology has been advanced by the introduction of economic assessments associated to technology. The most dominant work in this area has been in the QALY (National Institute for Clinical Excellence, 2011) as a tool which although not perfect provides some measure and comparator between approaches. QALY stands for Quality Adjusted Life Year. This calculates the cost versus the benefit of a new intervention in comparison to an existing therapy. The use of QALY has some limitation which have been documented around the gathering of data based on existing technology. QALY in some cases is struggling to address emerging technology which will require a rethink of the application of technology and its value for patients and may need further adjustment (Campbell et al., 2017). For example, new technology such as “companion diagnostics” allows for genetic or personalised diagnostics to determine if a treatment will be effective for your genetic profile. A cancer drug may not work on a percentage of patients with a specific gene expression. The identification of the gene may result in a decision not to treat with that drug. The decision not to treat is of value to the patient as a non-effective treatment is not used, therefore avoiding potential side effects, and the secondary approach can be considered for effectiveness in a shorter time window. There is additional benefit through the saving of wasted resource by the healthcare provider and patient yet the QALY doesn’t recognise this value and new measures are going to be needed (Husereau et al., 2014). This then creates problems of comparing a traditional technology with a newer companion diagnostic technology which has stratified the patients. Lee et al. (2013) suggests The QALY model for companion diagnostics would therefore need to be adjusted to take into account the whole cost benefit of both those who receive the treatment and those that have been excluded as a result of the test. For the adoption of technology of this nature all costs, including the identification of new costs and wastes due to the emergence of new biomarkers, must be under constant review and accounted for in the wider adoption and business case.

Data protection is an additional issue for widespread deployment of technology, use of data and trending of information. There is a lack of clarity on how to use personal data within the emerging solutions. In the medicine section 7.6.2, Fox (2015) Nature biotechnology article reported on the President Obama launch of a precision medicine initiative. While the initiative drew out the positives of a new medicines approach using technology it also identified some issues of curating and cleaning large data sets, gaining continued consent, fitting clinical ethics for research, patients maintaining control of their own data and the lack of focus of “data driven races” that go many directions at once. Data sharing and management is an issue today and is likely to grow as an issue as we move from big data to genomic data being a key part of our care pathway. Discussions at the World Innovation Summit for Health: Doha, Quatar in 2016 (which the thesis author attended see appendix A) extended the data questions to security and safety questions for individuals. Political shifts in volatile countries can be linked to ethnicity and the health requirement to capture your genetic details may provide unintended consequences of creating databases suitable for example to support ethnic cleansing. Even if it is clinically relevant the data risk may not acceptable to many countries with a troubled past or where the government has been shown to access data without permission.

In summary there are many opportunities in healthcare technology to address waste within the research questions and redefine patient value within long term care however technology brings with it some new challenges around adoption and ethical challenges.

Chapter 8 - Thesis Discussion

8.1 Introduction

Chapter 2-5 focused on understanding the Lean, healthcare and technology literature and chapter 8.1 provides a short summary of the purpose of each chapter.

Table 8.1 – Chapter Summary Reminder

Chapter	Purpose of Chapter
2	Literature review of Lean in the public services
3	Literature review of Lean in healthcare
4	Literature review of technology in healthcare literature with a focus on the UK and USA.
5	Theoretical development of the chapter 2-5 reviews and developed a theoretical model with gaps in the literature. This highlighted that healthcare literature was focused on healthcare providers rather than value for patients (Porter and Lee, 2013)

The literature review identified that Lean in public services was being deployed in a disconnected system of providers who often had limited process knowledge (Antony, 2015) and a lack of customer focus (Radnor and Osbourne, 2013). This creates waste rather than value. In healthcare the demand for integration reflects a growth in ageing citizens with long term conditions (Dannapfel et al., 2014). This is relevant for the prevention and management of long term conditions, as they require clinical intervention and therapy both in the hospital and in the community over a prolonged period of time. The literature reviews, also highlighted a gap for technology being used in Lean healthcare interventions identify waste, remove waste and improving value for patients.

A mixed method research approach was chosen to analyse the care pathway for cardiovascular disease as an example of a long term condition. This utilised the healthcare Lean wastes framework identified in chapter 3 to assist in identifying cardiovascular disease wastes. New waste activities from cardiovascular disease were also identified and recorded. The information on current activity focuses on the Northern Ireland cardiovascular disease healthcare delivery. It uses quantitative analysis which has been created from open data sources and qualitative analysis from focus groups and healthcare experts. Literature from working practice guidance and grey literature material were also analysed to provide a richer analysis of cardiovascular disease activities and related wastes.

This thesis discussion chapter brings together the literature and the research of cardiovascular disease from chapter 7. It will summarise the contribution to knowledge that have been made and revisit the research questions that have been laid out in chapter 6. These research questions are;

- How can Lean be adapted for long term conditions?
- How can healthcare technology assist in identifying and addressing Lean non-value add activities?
- Can healthcare technology from data focused technologies assist in redefining patient value?

To address these three questions, the thesis discussion will utilise the Lean literature five core Lean principles (Womack et Al., 1991) of; defining value, value stream mapping, making it flow, pulling to patient demand and continuous improvement. Within the five core principles, the research questions will be addressed based on the analysis from chapter 7 and the earlier literature findings. The structure of the discussion is presented in figure 8.1 with the sections references included. Question 1 will be addressed last to reflect the summary nature of the question and thesis.

Thesis Discussion Chapters Structure

Q1 - How can Lean be adapted for Long Term Conditions? *(8.7)*

Defining Value *(8.2)*	Value Stream Mapping *(8.3)*	Making it Flow *(8.4)*	Pull to Patient Demand *(8.5)*	Continuous Improvement *(8.6)*

Q3. Can Healthcare Technology from Data focused technologies assist in redefining patient value?

Q2 – How Can Healthcare Technology Assist in Identifying and addressing Lean non-value add activities?

Figure 8.1 – Chapter 8 Structure to Address Research Questions

8.2 Defining Value

In this section, the thesis discussion will focus on research question three which asked "How Can Healthcare Technology from Data focused technologies assist in redefining patient value". Defining value is the first of the five Lean principles (Womack et al, 1991) and this has been analysed in the healthcare literature and in the cardiovascular disease research.

While there are many examples of Lean healthcare deployments (Moraros et al., 2016), what is questionable is their focus on patient value rather than focusing on provider value. Where Lean tools or approaches are used it is often within the context of a specific silo of the patient journey and rarely representing the patients complete value stream. This is further complicated by a lack of understanding of who the customer is within a Lean deployment (Radnor, 2012). Porter and Lee (2013) reinforce this by stating that reforming healthcare has pursued the "wrong goal" or "narrow goals". The findings of this thesis are that Lean value is not fully considered in delivering healthcare and the implementation of Lean must start by defining value for the patient. In particular this applies to long term care patients who are likely to engage across a number of care providers. Within this gap, of value for a long term condition patient, the research has explored the activities and the healthcare technology which may begin to redefine value for a patient. The research question will be discussed using the structure outline provided in figure 8.2

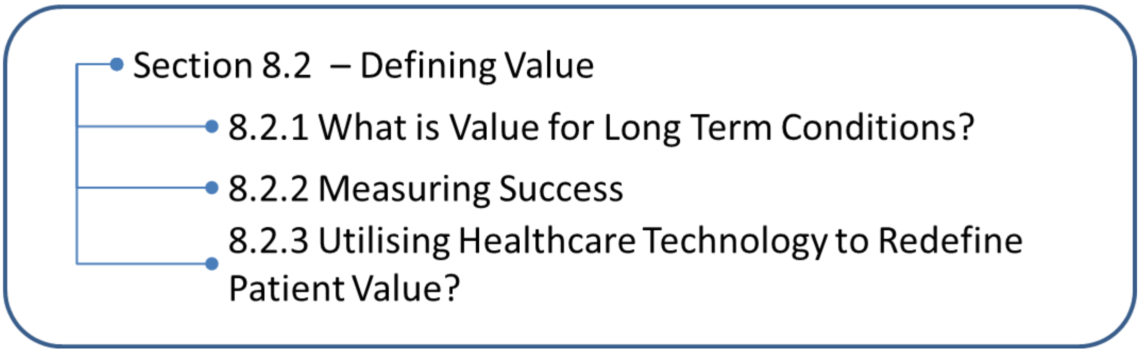


Figure 8.2- Defining Value Overview

8.2.1 What is Value for Long Term Conditions?

Value for Lean starts with a customer. A key discovery of the thesis in section 7.2 was that for Lean healthcare the customer was unclear, this was due to the separation between the consumer of healthcare and the payer. This thesis developed a position that the patient must be the Lean customer. Replacing the principle of the patient as the customer will ultimately results in the wrong goals for any healthcare system (Porter and Lee, 2013). Despite this emerging principle of the patient being the customer, there was an absence of Lean healthcare literature defining value for the patient and then creating the Lean value stream. The majority of Lean healthcare literature is focused on healthcare service providers which is only one element of the Lean customer value stream.

In addition to the lack of literature considering the current value stream there is emerging demand from long term condition patients which will exacerbate the situation and lead to overloaded emergency services. The lack of value stream thinking means that healthcare providers do not have visibility of the long term condition patient's interactions with the healthcare service and therefore can't plan accordingly. The data collection for the quantitative analysis reiterated this as there were no measurements reflecting the patient journey but only sections of the journey such as the time in hospital. The qualitative analysis confirmed this gap as healthcare providers had little concept of the whole journey for a patient, no access to data to understand it and no understanding of the impact of changing decisions made by commissioners. The care providers will not understand the data sufficiently to understand if demand increases at this time are causation or correlation. Cardiologists admitted that they had no understanding of the level of waits or delays and focused on the patient in the clinic in front of them. Performance improvement managers reported that they had a suspicion that commissioning decisions were influencing waits but this level of information was not available to them therefore they were not making decisions based on the full value stream. Cardiac nurses were again unaware of readmissions being a significant issue, reporting that they have been visiting patients around day 30 due to their workload despite the literature suggesting that patients readmit around day 16. Their focus on the next patient on the list removes visibility of the patient group across the value stream. In Lean tools the concepts of visual management across the value stream is frequently used to provide this missing visibility. For long term condition patients, visual management is not available along the value stream to the clinicians which means that issues cannot be quantified or addressed through continuous improvement. To illustrate this, a number of the qualitative analysis groups were shown data (Figure 8.3) which had been gathered through the quantitative analysis. They were surprised about the level of data available and some of the trends emerging. When asked for a potential hypothesis on the growth in waiting list demand starting around 2014, a cardiologist was able to put forward a number of potential ideas around the procurement from the independent sector and replacement of GP's with locums leading to more referrals due to the inexperience of the locums. When asked if changes in GP measurements in QOF during 2014 may have incentivised extra demand, he stated that he was unaware of the GP QOF information which he described as a "dark art" and unknown to him. He did believe that despite his lack of knowledge of what the GP does this would be a good hypothesis to test. The point of the qualitative analysis was not to explore the 2014 issue or do a route cause analysis but to understand the gaps in current knowledge and impact on the patient value stream. The current provision means that visual management was not available to them to make informed and collective decisions across the value stream. Changes to resourcing, procurement adjustments or commissioning decisions all could contribute to negative downstream impact on patients and clinicians without ability to measure and understand how to improve this.

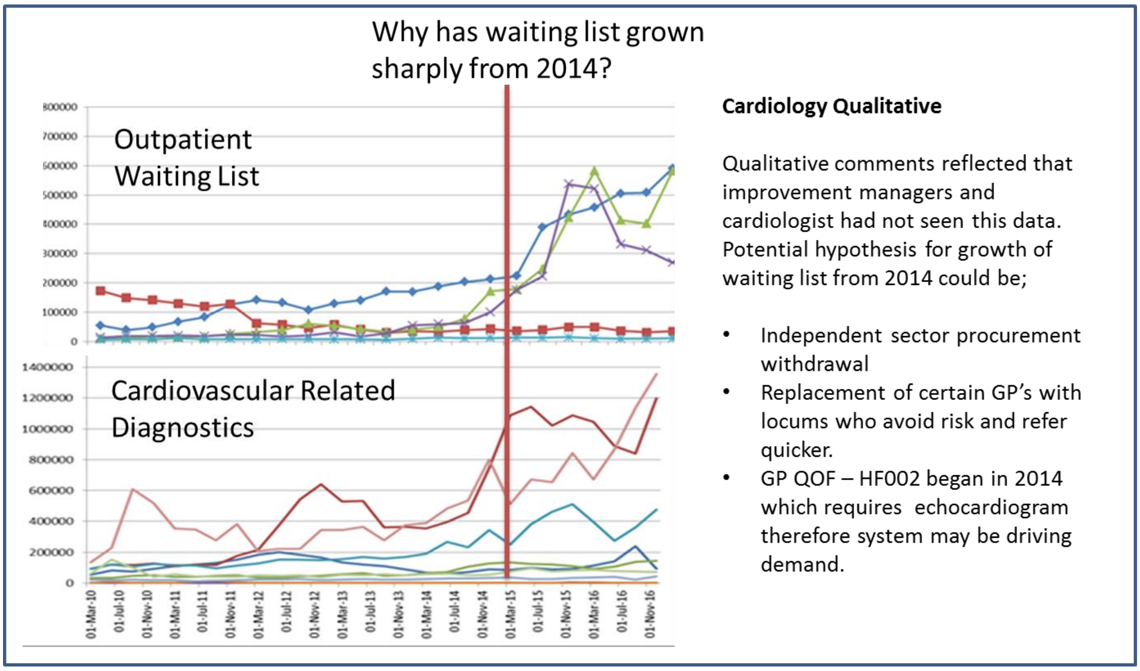


Figure 8.3 –Value Stream Continuous Improvement

Beyond the value stream, a patient contributing to their own healthcare value creation is a gap that has emerged in the Lean literature. Cardiovascular disease is defined as a non-communicable disease that can be prevented (WHO, 2017) therefore the clinician is not the only producer of value but the patient as well. Lean literature makes no reference to this and focuses on the healthcare workers activity. For long term conditions such as cardiovascular disease; diet, exercise and adherence to medication will result in the creation of good or poor health outcomes. Lean reform must address this co-creation of healthcare value where the patient is contributing to their own value. Linked to co-creation is a need for personalised approaches which understand the motivation and behaviour of individuals and tailor the interventions to the needs of the patient (Thompson, 2013). Similarly quantitative data from section 7.3 highlighted that specific patient groups may not be impacted by public health interventions (manual workers smoking).

Unmet value is also present in Lean cardiovascular disease treatment, in particular around choices a patient may make about treatment options. Unmet value is not a concept appearing in Lean healthcare theory but it reflects a patient value that has not been met. A patient may want to withhold, delay, and adjust treatment choice based on personal choices. In particular in the final stages of life where painful interventions may have a limited return when measured against quality of life or personal preferences. This emerged in both the qualitative clinician discussions and the heart failure nurse interview from the qualitative analysis as the cardiologists recognised that many signs are present that the patient is entering the end of life yet the clinician's instinct is to continue to treat the condition. One clinician described that "The patient will stop responding to the drugs and the biomarkers will not improve as expected. The evidence is there that the patient is moving to end of life. We can continue to treat them, but that might not be in the patient's interest as it may be better to manage the pain relief rather than treat". Despite value for a patient potentially being different than what is being delivered there is a lack of Lean literature or operational coverage of indicators or decision making tools that would assist this change in the value stream activities. Other examples of missing values included a link between psychological factors, such as stress, anxiety and depression and poor health outcomes. Diagram 8.4 summarises the missing value which has been found in the research.

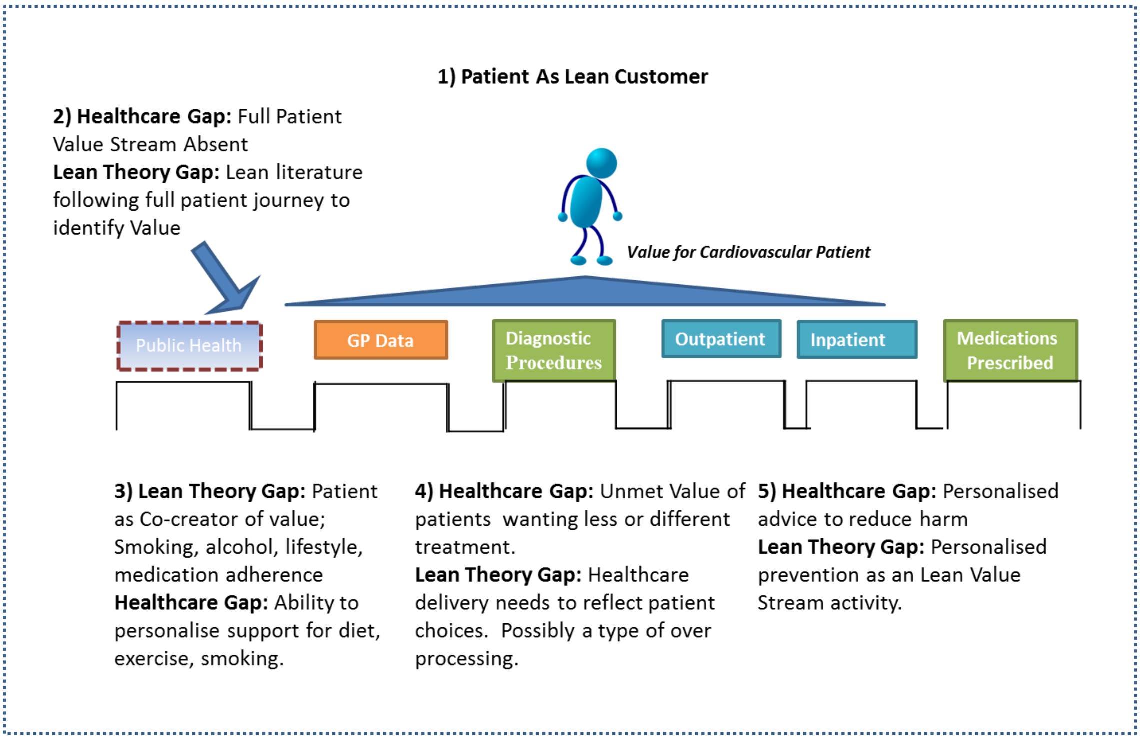


Figure 8.4 – Diagram of Missing Value

8.2.2 Measuring Success

Measurements in healthcare can reflect national priorities, short term politics and available financial resources rather than patient value (Ham, 2017). Throughout the research the Northern Ireland health service data has been used in the form of waiting lists, targets and activity. Many of these are not measuring patient value but some proxy of perceived patient value. This thesis would argue that this drives the wrong behaviour in the system as the providers do not focus on perfection as a Lean principle but rather on the performance metric. This reflects some of the earlier literature searches where Gubb and Bevan (2009) highlighted that Lean can expose “the fallacy of targets”. Similarly Seddon’s (2003) book freedom from command and control is critical of public service measurements that drive the wrong behaviours. Porter (2016) notes that in the USA healthcare providers work towards “the wrong incentives which reimburses hospitals for the volume of activity but not for value creation or outcomes. All these measures are based on activity despite a strategic interest in moving to outcome based care (Porter and Lee, 2013).

Examples emerging from the quantitative research where the measures may be driving the wrong behaviours include;

Public Health Measures – Smoking cessation quantitative data in section 7.3 in this thesis identified a year on year decline on interventions and the lack of progress in hard to reach high deprivation communities yet this was not highlighted in public health reports which congratulated itself on a job well done as the total smoking figure had reduced. Similarly, obesity measurements were halted midway through the longitude data despite them revealing a problem. It would appear that success in the measures from a PR perspective seemed more important than the data driving improvement in a Plan-Do-Study-Act improvement approach.

Hospitals and Diagnostics – Targets do not reflect patient value. For example the 6 week target or reporting on a diagnostic test in 4 weeks reflects resourcing issues in the system and not patient value. Targets such as 75% completed in 6 weeks again reflect a large failure for 25% of the patients even if the target did represent patient value. In a resource constrained organisation a better driver for behaviour would be to reflect on the demand and activities rather than put measures that do not reflect patient value.

Missing Measures – Many of the patient values around quality of life or patient outcomes are not measured. The focus on measuring activity and lack of outcome focus means there is very little understanding of the impact of interventions. Similarly the medicines outcomes are not measured therefore the high cost of medicines has no understandable return on the investment in patient value. There are known issues emerging in the qualitative focus groups around under prescribing, overprescribing and toxic impact of most medicines but no quantifiable measures available.

Measuring the Cost of Waste – There is no information in the system on the cost of the Lean wastes. As a simple example, the waiting time for an outpatient appointment is clearly recorded but there is no assessment of the cost of managing this patient. The patient will likely become a more costly emergency patient or will absorb temporary cost through medicines or additional GP visits. This means that economic choices about investing to save are not available.

8.2.3 Utilising Healthcare Technology to Redefine Patient Value?

Research question 3 asked if health technology from data focused technology can assist in redefining patient value. To answer this there are three specific areas of technology interest in redefining value which are;

- Data analytics
- Machine learning
- Decision support

These will at times overlap but for the purpose of this thesis they will be discussed separately and illustrated in the diagram 8.2.3.

Data analytics and the sharing of information through electronic systems have the potential to contribute to redefining value. The ability to see across silos of healthcare providers to understand the journey was absent in a large amount of the activities but with use of technology this could be fully realisable. The use of a new electronic health record which has been implemented across the 5 HSC trusts over the last 5 years was praised in many of the qualitative groups for sharing data. The concept of using this to see groups of patients across the silos was not available as the system looks at one patient and doesn't focus on waits or delays. This is not a technical constraint but an unmet need that could be addressed with technology. This would require significant work to address barriers which emerged while investigating access to cardiology data for quantitative analysis. The systems meta-data language and general expertise of working across care organisations was very limited and required input from a number of experts for even basic analysis. When this long term condition value stream is available through technology, Lean concepts such as visual management and continuous improvement could be aided. It should be noted that the combination of technical capability, Lean knowledge and healthcare knowledge would be required to make this a reality.

Machine learning through longitudinal databases of healthcare data could also begin to address value through personalisation of healthcare, understanding interventions and assisting in developing the concepts of co-creation for value. Machine Learning could be used to predict outcomes, personalise, and consider preferences for individual patients. It could also start to quantify the risk or impact of interventions based on real data from patients in real time. From this it is possible to predict what the potential outcomes are likely to be and to personalise the care interventions. Machine learning is used in other sectors to understand engagement with retail, websites or manufacturing performance but has had limited application to healthcare despite the known issues of areas such as exercise adherence, medication adherence and smoking cessation. Machine learning works by defining the outcomes and identifying the optimum path that helps lead to these outcomes and this could be applied in healthcare. The following machine learning outcome could be pursued to increase patient value.

- **Public Health Measures –** Capture data to support appropriate interventions through social media data, tailor messages to specific communities and target engagement messages. This could utilise machine learning to understand the approaches which deliver the best outcomes.

- **Hospital and Diagnostics** – activity and wait measures can be replaced or complimented by value stream data in electronic health records to join patient journey data across providers. Rapid diagnostics can be used by decision support and point of care diagnostics to remove waiting, batching and transportation wastes.
- **Missing Measures** – Technology can support medicines outcomes and adherence issues to address known wastes in the system. Machine learning can assist in understanding toxicity and non-responder patients to avoid waste in the care delivery.

The final technology for considering the research question is from decision support technology. Within this, many more technologies such as diagnostic data devices, clinical monitors, vital signs devices and information sources can feed data in on the patient's condition, history, and genetic profile and life choices. Collectively these data points can assist in defining the likely choices available to a clinician and patient. This decision support can be used to ensure the clinician has considered all the patient data but also to provide information on options for the patient to allow more control by them. For example decision support may lead to presenting data that specific treatment may reduce mobility which may be more important than pain management. A patient may want to choose between less mobility or the same level of pain based on their personal preference.

Radnor (2013) warned that Lean will fail unless there is a clearer focus on the customer (or patient) value. Technology provides an opportunity to address this failure by capturing and quantifying value which can then be used in the continuous improvement element of assessing if value has been delivered. This links back to a need for both Lean and technology together. The use of technology to assist in redefining patient value is illustrated in figure 8.5

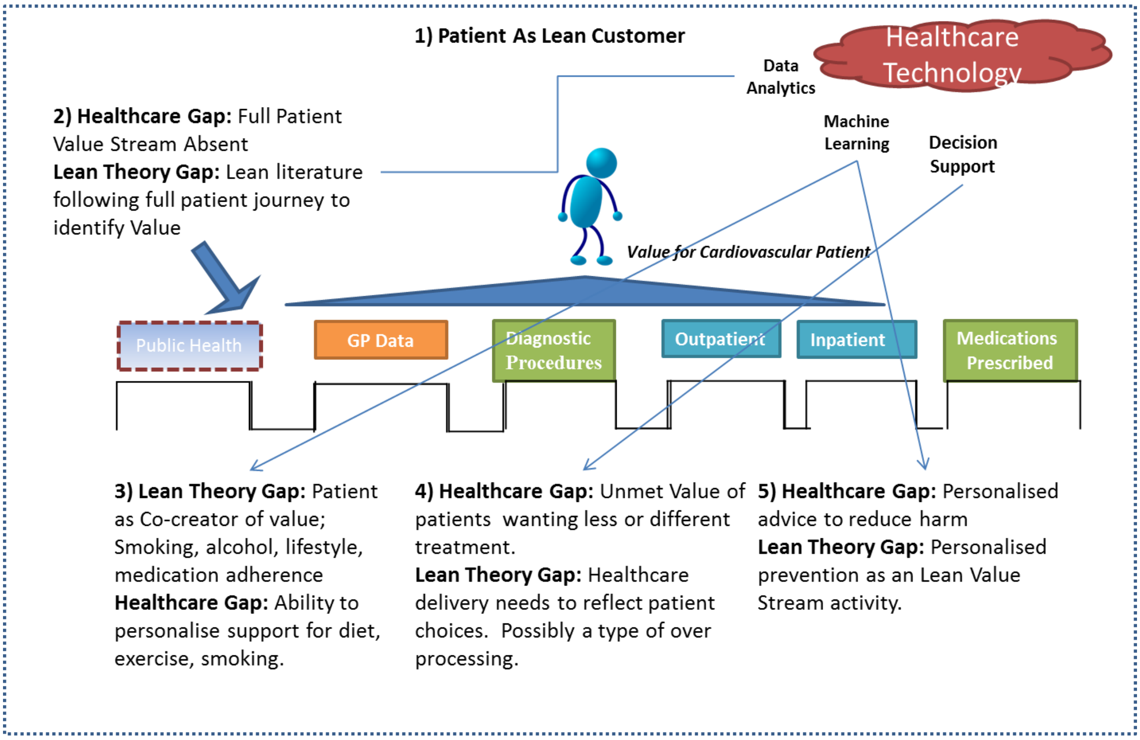


Figure 8.5 – Use of Technology to Assist in Redefining Patient Value

8.3 Value Stream Mapping for Long Term Conditions

The second of the Lean principles relates to value stream mapping (Womack et al, 1991). Addressing value stream mapping in the cardiovascular disease research provides an opportunity to consider research question 2. This asked how healthcare technology can assist in identifying and addressing Lean non-value add activities.

Prior to discussing value stream mapping across the cardiovascular disease, it is worth highlighting the complexity of crossing the value stream of the cardiology patients. To put this in perspective, the data on “New to Review Comparisons” which is one of the many measures in the hospital data, required navigation through over 650 pages of other data. The author of this thesis has significant experience in navigating health data and systems for the Northern Ireland health service. This is highlighted to emphasise that although data may reveal clinical and operational insights, this is not easily available even if the clinicians know where to look and this will not be navigated in a rapid improvement or Kaizen events (Moraros et al., 2016). Technology will be needed to assist in navigating the value stream in ways that are not available to Lean deployments with sticky notes, flip charts and good will. The current Lean deployments reflect this limitation by keeping to small section of the value stream. In chapter 6, the honest broker service (service providing anonymised data in the HSC) data was described as being of value but difficult to access due to the ethics application requiring clear outcomes prior to approval. This highlights that data which assists in drilling down into patient behaviour and outcomes is difficult for Lean research as often the explorations require an ability to navigate organisations and ethics barriers. Early explorations with the Honest Broker Service also revealed that diagnostic data from medical devices is not stored and therefore not available in the health service for comparison. The diagnostic procedure is completed and reported but there is no storage of the test data electronically. Opportunities to compare patient's data using ECG (Heart Rate Data) information are not available today.

While the complexity is a barrier or challenge for long term conditions, continuous improvement across the full journey is possible with technology. The data could also begin to create full cost of the system and identify areas not known in the measurements. For example, warfarin (blood thinning medication) is known to have costs in the community to monitor that the right levels are being used and the patient's body is responding but this is not part of calculation of medicines costs today. This data would provide opportunity to seek improvements in the system based on more complete pictures with evidence. Emerging care models could also be further explored and expanded such as Hospital at home or Step down care as the full cost and outcome of the alternative could be compared.

In summary, the creation of value stream maps based on available data across long term conditions is likely to be too complex without the aid of technology. Many data points from cost or deep clinical symptom information may be useful to the value stream maps but are not available today. Developments could make this valuable information available in the future. The combination of the current data and future data could provide significant opportunities to improve and explore various emerging care models.

8.4 Making it Flow

As the third of the Lean principles relates to understanding flow (Womack et al, 1991), this section discusses flow in the cardiovascular disease research to provide an opportunity to address research question 2. This asked if healthcare technology how can assist in identifying and addressing Lean non-value add activities. Specifically this addresses the waste being created in the care delivery.

Analysis of Lean healthcare activities in Chapter 3 identified Lean wastes and a template of healthcare wastes created. This was then applied to the cardiovascular disease areas throughout the analysis to model Lean for long term conditions. 8.2 summarises the findings with the left hand column being from the literature review chapter 3, the middle column from cardiovascular disease research in sections 7.2 to 7.6 and the right hand column addressing these wastes from research section 7.7.

Table 8.2 – Waste in Cardiovascular Disease as an Example of a Long Term Condition

Healthcare Failure Area Identified in Chapter 3	*Description*	*How Can Technology Identify or Address Waste*
Waiting times	Unplanned admissions which includes emergency admission and readmissions. Evidence of high unplanned admissions for cardiovascular disease from the community. Quantitative data highlighted growing waiting lists to outpatients, diagnostic test, diagnostic reporting	Technology to address monitoring of those on waiting list and discharged at high risk. Visual management technology of waiting time over time could be used in root cause analysis and continuous improvement across value streams.

	and hospital procedures. Potential link to changes in commissioning decisions.	Point of care diagnostics to rule out patients not needing further investigation.
Delays	Awaiting test results, interventions and next steps can cause deterioration in conditions and poor quality of life while awaiting intervention. Delays due to cancelations.	Electronic referral to remove delays in information exchange via electronic health care records. Decision support to provide intelligent planning for avoiding cancelations.
Activity Transaction Speed	Diagnostic procedure may not be available near the patient or the lab therefore increasing diagnostic turn-around time.	Point-of-care testing can remove delays in diagnostic information therefore accelerating the decision time for beginning treatment.
Diagnostic	Evidence of duplicate tests, over-ordering of tests and tests which are driven by commissioners rather than patient value. Batching of tests to go to regional labs and no test logistics over the weekend result in lost patient value. No diagnostics to detect if drugs will work with the patient genetics.	Technology available to provide rapid diagnostics or point of care diagnostics. Remove waiting and need to batch tests. Emerging companion diagnostics provides opportunities to diagnose the impact of the medication
Medical Complexity	Increasing evidence of patients with a number of long term health	Technology can assist in clinical decision support for

	conditions can result in conflicting treatment – chronic kidney disease, diabetes, cancer and asthma evident in the causes of readmission literature often linked to the medication conflicting and causing symptoms.	complex decisions requiring insight from different clinical specialties.
Additional Healthcare Visits	Inconsistent levels of review appointments leads to questions on over-processing or under-processing patients in certain hospitals. Incorrect or ineffective medicines leading to additional appointments with doctor or emergency readmission to hospital.	Technology and Lean can monitor adherence to best practice guidance. Technology can address medication monitoring.
Co-ordination of Healthcare resources	Coordination of care does not cross providers and provide patient value. Readmissions reduction requires coordination of service provision to ensure the patient has all requirements covered.	Shared care records, activity lists, shared notes; shared medication record and shared allergy information all contribute to the coordination of staff.
Stress/overload of staff	Evidence of lack of capacity to deliver value for the patients. Demand is significantly outstripping capacity resulting in waiting lists.	Technology to assist in removing demand and identifying where activity is not leading to improved outcomes.
Repeated Procedures	Data captured in the community not shared with hospital or social care providers requiring repeated test or data capture.	The use of shared ICT systems such as regional PACS systems (shared diagnostic information) and Electronic Health Record has

		been reported in qualitative analysis to reduce repeated procedures as clinician have access to previous test results. Further opportunity to reduce waste available.
Cost	Evidence of not addressing overall value leading to higher costs base as care in community deemed to be more cost effective. (Mendoza, 2009) High cost of drugs and hidden costs of having to monitor biomarkers for specific medications that can be dangerous, addictive or have negative side effects. Overprescribing medication.	Technology emerging to assist in hospital at home. Medicines adherence technology available.
Quality	Maintaining current best practice an issue for clinical guidance due to the number of guidance documents and rate of change. Readmissions of patients can be regarded as a quality issue in a number of cases. Further treatment is required as the underlying issue has not been addressed or the therapy which has been provided is not suitable to address the condition.	Clinical decision support technology.

Emergency Admissions	Issue of ED vital signs monitoring not revealing heart attack reflects limitations. High volumes of readmissions. Significant numbers of emergency admissions are linked to medication issues.	
Medication errors	Every medication does not work for a % of patients (non-responders) or can have toxic effect. Medication titration a key issue for readmissions. This was revealed in qualitative discussions where it was shared that patients need close monitoring on discharge. Evidence of doctors prescribing medicines based on advice that is outdated. Drugs selection not considering other health conditions such as diabetes, asthma or kidney issues. (co-morbidity).	Companion diagnostics can identify the patients who will respond to medication and non-responders to remove errors. (Lee, 2013) Medication compliance technology with IOT/smart homes technology providing some options around medication reminders.
Infections	Hospital acquired infections is related to some of the reasons for readmissions. In particular hospital acquired infection is a specific waste.	The use of technology may be a source of some infectious disease spread as machines and technology are passed between professionals. Data analytics and machine learning can identify patterns of infection, staff behaviors

	in a hospital that may have led to infection spread, patterns of drug dispensing that would encourage drug resistance leading to infections and data relationships to environmental factors.

What is clear from the research is a number of wastes presented are emerging due to a lack of coordination across the silos. Lean healthcare literature has tended to focus in the silo and would not identify these long term condition wastes. For example prevention, readmissions and understanding the commissioning decisions impacts on other parts of system. These wastes require interaction along the long term care value stream.

Emerging from the research is technology that can address waste where there is complexity that requires more than the current Lean healthcare interventions. Related to these waste can be the need to understand the demand in the system and pulling to patient demand which are addressed in the next section.

8.5 Pull to Patient Demand

The fourth of the Lean principles relates to pulling to customer demand (Womack et al, 1991). This section analyses the cardiovascular disease demand to provide an opportunity to consider research question 2 which asks how can healthcare technology can assist in identifying and addressing Lean non-value add activities.

Pulling to customer demand may seem somewhat alien to healthcare providers in the UK as the public health provision often means that they are working on waiting lists which implies demand has outstripped supply. Understanding demand is however a gap in Lean literature as often there is an assumption that the demand for a service is linked to value. Demand is more complex in cardiovascular disease treatment or healthcare in general, than in other industries. Clinicians have many choices in providing tests and therapy options which can result in over processing or alternatively result in a missed clinical intervention. Figure 8.6 provides a summary of the demand experience in the cardiovascular disease found in this thesis.

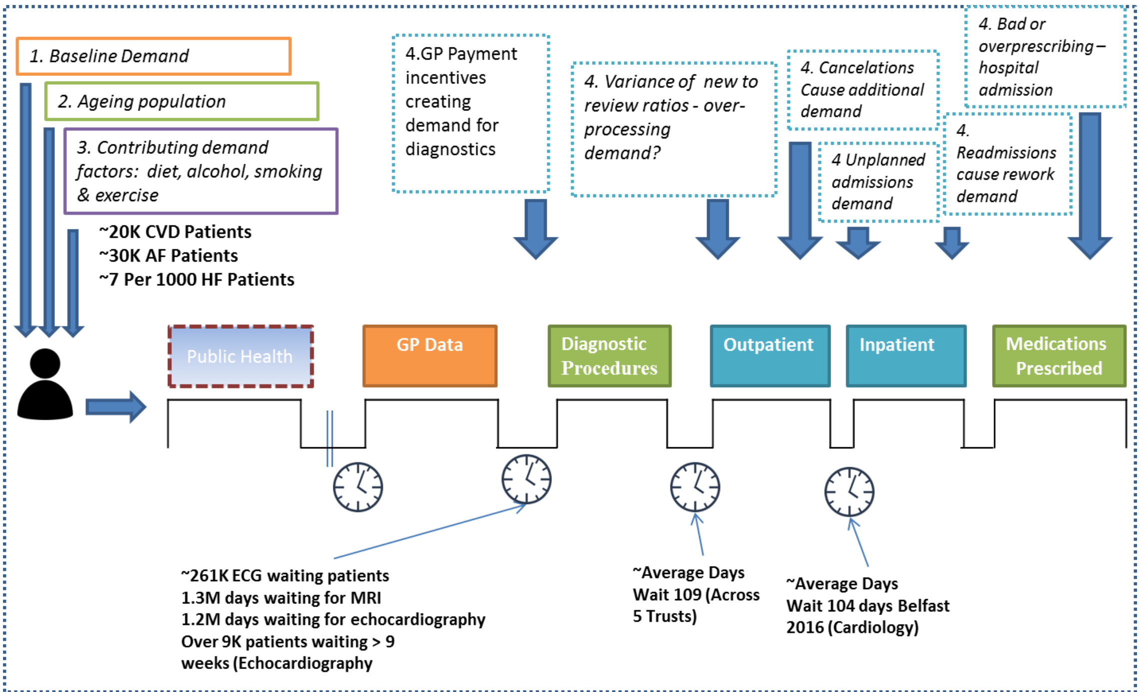


Figure 8.6 – Understanding Demand in Long Term Conditions

What emerges in the research and illustrated in figure 8.6 is an understanding of demand for long term condition services. Value based demand can be seen within the baseline demand for people with a cardiovascular disease (1) and additionally there is a demographic shift through a growing ageing population (2) which is creating additional value based demand (Dannapfel et al., 2014). Demand which is not value driven has also been identified in the research as preventable demand (3) and Lean waste demand (4). A number of these are not addressed in Lean healthcare literature such as GP incentives driving additional demand for diagnostics. This could relate to the Lean healthcare literature being focused on one element of care delivery and not seeing the implication of changes in demand in another part of the system. This reflects John Seddon (2003) work on failure demand in public services where bad levels of service in one client facing section results in a demand elsewhere. Preventable demand due to factors such as obesity is documented in healthcare (World Health Organisation, 2017) but not documented in Lean healthcare. This could be developed further as a Lean waste category and provide a contribution to Lean literature.

Healthcare technology could begin to identifying and address Lean non-value add activities illustrated in Figure 8.6. As preventable disease is a large element of the long term condition waste (World Health Organisation, 2017), data related technologies linked to prevention have an ability to personalise the patient engagement and address their needs in a way not available today. Visibility of the full patient journey could assist in creating improvements, monitoring technology for patients outside of the hospital could bring intelligence to earlier intervention to prevent unplanned admissions and decision support could be used both to address the issues of bad decisions and develop adherence to best practice. This was emphasised in discussions with the Cardiologist where it was revealed that there is limited to no intelligence beyond the initial referral letter about the patient or their condition.

"The patient may turn up in my outpatient clinic after being on the waiting list for many months with no knowledge of why they are there or if the referral is still needed. Other patients will end up in an ambulance and bypass my outpatient clinic. We don't have information on either beyond the initial referral letter"- Cardiologist, Western HSC trust.

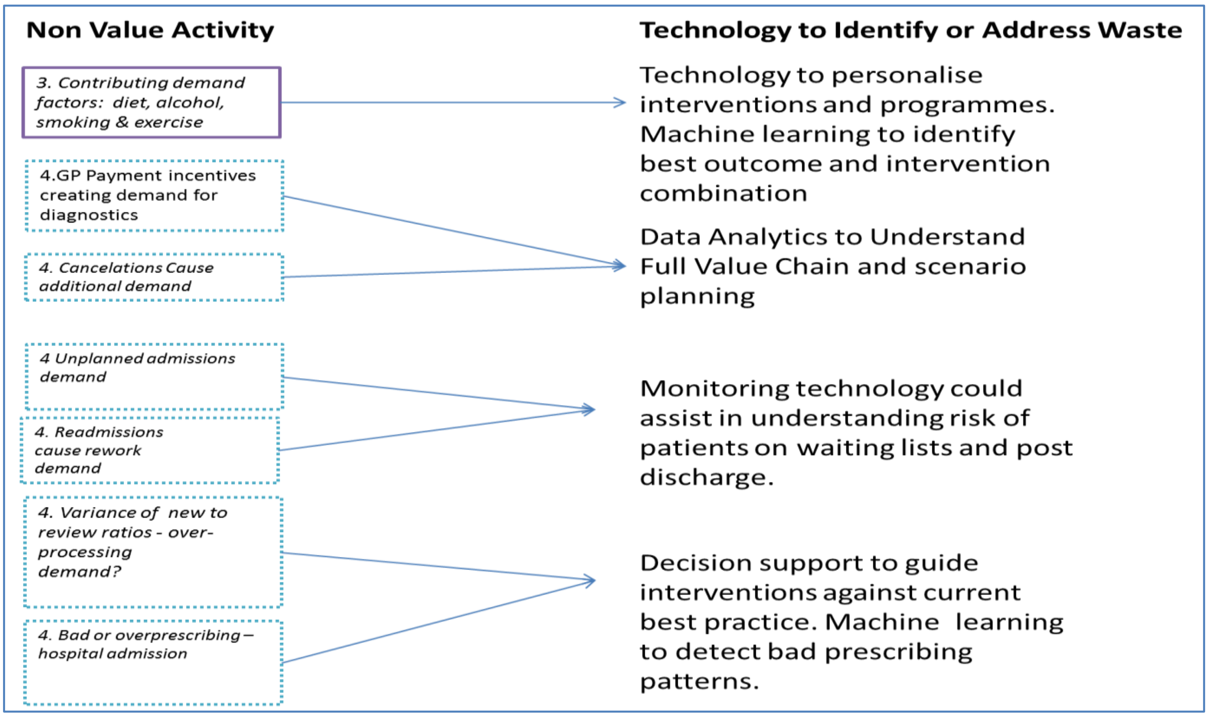


Figure 8.7 –Technology Opportunities in Long Term Condition Demand (Non-Value Demand)

Many of the technologies mentioned in figure 8.7 provide an opportunity to create visual management and understanding of data within a long term condition. The data in itself does not improve the care delivery and is only a tool. Continuous improvement must therefore adopt the technology opportunity and utilise this within a wider programmes of improvement activity. The next section addresses continuous improvement.

8.6 Continuous Improvement

The fifth of the Lean principles relates to understanding perfection or continuous improvement (Womack et al, 1991). This section seeks to discuss continuous improvement in the cardiovascular disease research to provide an opportunity to consider research question 2 which asks how healthcare technology can assist in identifying and addressing Lean non-value add activities.

Two key areas emerge from the research, which are around the short sighted nature of Lean deployments which lack a continuous improvement aspiration (McCann et al., 2015). Linked to this is lack of sustainability for improvements that have been made. The sustainability issue, although related to continuous improvement emerged heavily in the qualitative analysis as a key criticism in Lean deployments with the improvement managers (Section 7.5.3). This can be partially linked to the fact that there is no definition of a Lean deployment (Samuel et al., 2013). Deployments which are labelled as Lean may be short term improvement initiatives to address a specific budget or demand pressure with no view or plan to embrace continuous improvement. Additionally the lack of capability building for continuous improvement is a factor in addressing both continuous improvement and sustainability (Smith, 2016). Capability and organisation buy-in to make and sustain improvements was also identified in “Data Analytics Workshops” where it was recognised that even if cost savings and improvements could be identified by technology the change management roles were not available to implement and manage the changes. In particular, complex changes that will cross organisations or departments require engagement skill sets that are not readily available. This is highlighted in the Accenture (Global professional services & Technology Company) quote below.

"It is important to engage clinicians, health managers and health oversight bodies to get the most out of analytics. Leveraging their different perspectives on data will help deliver richer solutions and deeper insights" – Kevin Duffy, Accenture Health and Public Sector Lead, Northern Ireland.

As noted above, the opportunity is not in a short term fix but requires the introduction of a continuous improvement cycle which is targeting outcomes rather than activities. Smoking cessation being an example of this within areas of high deprivation as non-smoking clinics (activities) or other approaches appear not to be having a significant impact on non-skilled workers as noted in section 7.3.3. however a continuous improvement approach could utilise technology to iterate and change approaches to maximise outcomes.

This reveals a question about if technology can be used to firstly monitor outcomes rather than interventions over a longer period of time and secondly can technology identify patterns of intervention that lead to better results through approaches such as machine learning. The measurement of outcomes is missing for both medicines and preventative healthcare activities as the full patient journey data is not available. For example, we may know that a patient has been prescribed a medicine but not understand if the medicine worked. This means that the medicines effectiveness is not known for this patient but also it is not known for other patients also taking the same medication. Technology has opportunities to develop continuous improvement cycles in areas such as health improvement interventions (smoking cessation clinic), self-reported reported outcomes (e.g. exercise and diet) and medicine that lack evidence of the real outcomes of the intervention over a longer time period.

Technology also has the potential for continuous improvement to understand variance in service delivery. The data in chapter 7 revealed significant variances across trusts with “new to review” having substantial variance in the ratios with a difference of approximately 29%. This implies that one healthcare trust is seeing their patients a significantly larger amount than another trust and this will have a knock on effect on the available new clinic slots. When looking at one year we find that a minimum 43% and maximum 72% during the time period. The Western Trust and the South Eastern Trust are the outliers at 42% and 72%. It is possible that when looking at these Trusts, the services have been reconfigured in ways which explain and justify the difference however there is still a question of identifying best practice for outcomes and costs which are only going to be available as part of continuous improvement cycles. Similarly examples in the data show where a trust has lower cancelations which could be investigated for cause and effect. Lean is focused on scientific management and this reflects opportunity to improve which has not been realised.

Linked to the activity variance is the adoption of best clinical practices or medication prescribing patterns. NICE clinical guidance (NICE, 2017) as highlighted in the hospital care section of the thesis is a positive step towards standardisation which would be supported by Lean however the sheer volume and changing nature of the guidance makes it impossible to monitor or deliver adherence to the guidance. The NICE guidance is however large in volume and constantly changing therefore leaving significant room for error. In addition, the combination of diseases is making the guidance more difficult as the clinicians must take into account both the presenting disease but also the other conditions and their response to the medication or treatment. Technology provides opportunities for decision support to address this. Complex decision making could be supported by technology and reminders or alerts could be tailored to the patient and in support of the clinician.

8.6.1 Sustainability

While Lean has short term positive results which have been published (Burgess and Radnor, 2012) there is a lack of quality literature which gives evidences of the benefits of Lean and the return for investing in Lean programmes (Antony et al., 2016). Additionally the topic of sustainability and scalability emerges as literature suggests that the improvements can become eroded over time and result in the perception that Lean is a management fad to be weathered rather than adopted (McCann et al., 2015). There is a lack of ability to sustain improvements and a need to engage people and leadership and not see the change phase as the end (Lucey et al., 2005). The ability to translate the improvement to business as usual and deploy across other locations is rare and difficult. Initiative such as the Sustainability and Transformation Plan (STP) from NHS England have highlighted this gap and the intention to address this (NHS England, 2018). Where Lean has failed however in sustainability, technology has the opposite issue as technology which has been adopted and deployed becomes the operational standard and can be difficult to replace. Many hospitals report on systems that are 20-30 years old and refer to the difficulty of replacing legacy systems. Lean therefore has a potential to be a tool for identification of waste with technology as a tool for sustainability. Examples of where this merging of thinking could occur include;

- Visualisation Dashboards
- Value Stream Reporting
- Evidence Gathering
- Addressing Waste
- Quantifying Waste
- Standardisation
- Continuous Improvement

8.7 Summary, Adapting Lean for Long Term Conditions

Returning to research question 1, which asked about how Lean can be adapted for long term conditions? The thesis research analysed cardiovascular disease related activities in the various silos of care provision and sought to understand the link between them that represents the patient care pathway or in Lean terminology the value stream.

Lean in a healthcare setting has been proven to be effective where it has been deployed. Lean literature has widespread use of Lean in healthcare as a performance management tool. Radnor's (2010) review of business process improvement methodologies in public health services highlighted Lean's use in many locations including Bolton, Scotland, Australia and Nebraska. Moraros et al. (2015) article highlighted that a large number of articles from Lean and healthcare were available but was critical of the number which had been peer reviewed with quantifiable data. The articles do provide evidence of removing steps, reducing waiting times, rapid improvement events and less space use and fewer resources being used. The healthcare deployments have focused on provider rather the patient. This limiting of scale and scope has ultimately developed additional wastes as silo based providers seek to enhance their own service and meet organisational goals without keeping patient value at the centre of service design. Long term conditions will cross the silos of healthcare provision and addressing patient value will require Lean programmes which reach beyond the silo of a hospital ward or GP surgery. Some of the main wastes emerging from analysis of cardiovascular disease as an example of a Long term condition include;

- Prevention Waste
- Public Health Waste
- Personalisation waste
- Cancelled appointments

- Medicines Outcomes
- Unplanned Admission

Despite these wastes there is little consideration of utilising technology to identify patients in the community on a waiting list about to be admitted as an emergency unplanned admission. Technology could be used to do predictive analysis of large data sets yet there is no predictive use case consideration in Lean healthcare literature. Cancelations cost the healthcare service a significant amount of money yet technology could address this with more personalisation of the engagement with the care provider. Community based data collection and machine learning from wider data sets could assist in understanding changes to a patient that can identify early intervention opportunities. In addition machine learning linked to non-healthcare data, such as weather and air pollution could assist in identifying changes that may lead to worse health outcomes such as respiratory condition escalation. Combinations of data collection and machine learning could develop intelligent waiting list which prevent unplanned admissions and reduce cancelations.

Classic Lean car manufacturing lines had quality failures as a core focus of Lean manufacturing with the “Andor Cord” to stop the process until what was failing was resolved. There is no equivalent in healthcare terms and although people are not machines and the next emergency victim can’t wait for a meeting there is limited exploration of the root cause analysis or the lessons to be learned. Waste within the cardiovascular disease value stream there did not have lessons learned of failure or root cause analysis. Technology could assist in providing decision support for clinicians dealing with increasingly complicated symptoms and co-morbidities. Additionally monitoring decisions for variance from best practice to identify training opportunities would be possible.

Specific bio-markers and risk factors are known which could be used to target both planned discharge and monitoring in the community to avoid readmission. Technology exists that can measure various bio markers and vital signs at the point of care or via mobile devices more easily away from the hospital. There has been a limited use of data to put in place actionable predictive models which identify patients at high risk of readmission patients.

Patient engagement and empowerment are both possible through technology. Education and the patient's opinions about "how they feel" could be captured and addressed remotely to both address concerns and also alert to potential changes highlighting a need to intervene. Education could potentially be tailored to the patient's ability to absorb the information and the timing of when it is relevant rather than a tsunamic leaflet overload at discharge. Equally peer-peer communities have proved successful in educating past clients on how to adjust to life with a condition and providing "life-hacks" which go beyond the public health notices which can be difficult to translate to living with a condition. Empowering patients - increasing the role and the responsibility of the patient is vital in providing positive outcomes. Diet, exercise, activity, medicines compliance and monitoring of a patient's own vital signs are essential but can be challenging both for professional and patients. Tools to support self-management, improve understanding, increase adherence of patients, support care givers and provide a continuum of care are needed.

8.7.1 Validating the Model in Practice

The model that is being proposed challenges the current method of Lean healthcare reform which focuses on reforming a provider. The later qualitative analysis work during the thesis has validated and refined how a new model could be implemented and what would be the steps to implement a new Lean Healthcare Technology model with various healthcare leaders.

8.7.2 Barriers and Boundaries for Technology

A concluding remark for the thesis discussion is that technology has been explored as a very positive opportunity for change but it is recognised that it does have barriers and boundaries. The ethics and ownership of personal data is a key area for focus impacting decisions on the sharing of data within care professionals and also with external research and commercial organisation. The ethics of ownership of genetic data is an area of emerging interest as the longevity and implications of the data has far reaching implications for the citizen today, potentially for the rest of their lives and potentially to their family. This may also have different implications in different countries. Qualitative analysis in Qatar realised that ethnic minorities in countries which have been subject to political uncertainty are particularly concerned about the use of genetic data for health as this can reveal ethnicity which may have personal security threat implications in the hands of a volatile government.

Technical maturity of communication, quality of readings, battery power and security are all constant issues being considered in developing products. A nurse that cannot get a connection for the device will quickly discard the device as not working, or a doctor receiving too many false positive messages will abandon the device as inaccurate. Technology adoption therefore must seek to ensure usability and robustness is guaranteed.

Chapter 9 – Revised Theoretical Model, Thesis Contribution and Conclusions

9.1 Introduction

The thesis has defined the current practice of Lean healthcare through a critique and synthesis of the literature, identifying significant gaps therein in relation to the delivery of value for patients and gaps in the use of technology focussing on Lean wastes in healthcare delivery activities. From this review and critique of the literature an initial theoretical model was identified (Chapter 5, Figure 5.3) and through the research (Chapter 7) and discussions (Chapter 8) a revised framework has been developed which focuses on the emerging needs of long term condition patients. This section discusses and explains this revised theoretical, framework illustrating how the aim and research questions have been addressed within the framework. The chapter also details the original contributions made by the thesis to knowledge and practice.

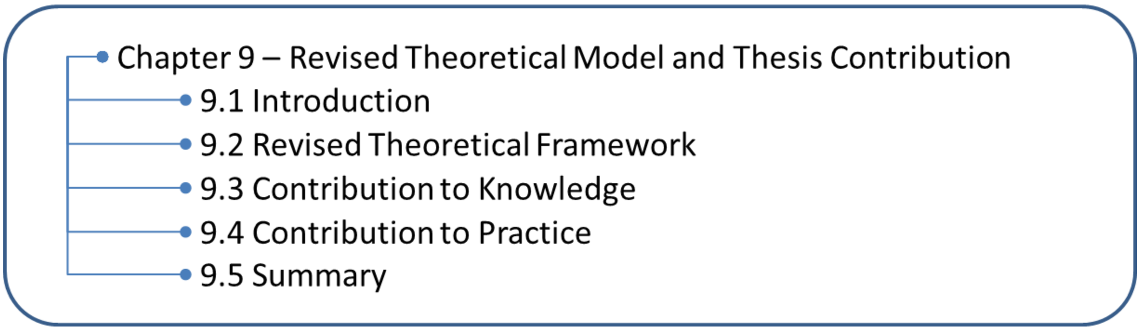


Figure 9.1 – Chapter 9 Overview

9.2 Revised Theoretical Framework

The development of a theoretical framework for Lean healthcare technology models which utilises the learning and approaches of Lean and opportunities presented by technology was the fourth objective for this thesis. This was developed by analysing the current practice from

Lean and technology literature to fulfil the requirement (Objective 1) to then develop an initial theoretical framework (Objective 2) to guide the empirical research which focused on cardiovascular disease as an example of a long term condition (Objective 3). The development of the theoretical framework recognises there was three phases with phase 1 being the current Lean healthcare provision, phase two being an initial framework based on assumptions and the phase 3 being a revised framework which has been developed based on empirical research as based on chapter 7 and chapter 8 The essence of this further conceptualisation is developed throughout chapter 7 and chapter 8 in line with the theory building methodology outlined in chapter 5.

The current Lean healthcare provision was found to be provider focused on a ward, an ED department, or group of staff, but not around a patient (White et al. 2017). There is no view available across the patient value stream from a GP through to diagnostics, hospital treatment and monitoring the patient's condition in the community as Lean is applied to the hospital not the patient (Mannon, 2014). This gap is exacerbated when looking at a long term condition-based patients journey where the current system measures starts and stops in line with provider metrics (section 7.5.3), turn-around times for diagnostic (section 7.4.3) and fails to address full patient value. Complexity in healthcare across the value streams appears to be a contributing factor with less success for Lean for more complex interventions (Mazzocato et al., 2014). The use of technology has emerged in the current healthcare framework as technology was absent from the majority of Lean literature even though it was emerging in healthcare improvement initiatives to address quality, reducing error, increase productivity and support best practice adherence (Seblega et al., 2015).

The initial framework (chapter 5, figure 5.3) was developed to fulfil objective 2 and was presented in chapter 5. Within this framework a patient value stream for long term conditions was identified which attempted to join the patients activities across the care providers. Within this initial framework was also a recognition that consolidated data utilising healthcare technology could attempt to identify and address known wastes. The known wastes had been consolidated from Lean healthcare literature. The initial framework also recognised that by creating and analysing the long term condition value stream that new wastes would be identified. Additionally, opportunities for technology to address waste would be identified as literature had indicated that opportunities existed in the use of large data sets to support the development of evidence and decision making (Riezebos and Klingenberg’s, 2009). The potential for big data analytics to support rapid improvement events was also recognised in the development of the initial framework (Bowerman and Fillingham, 2007).

The third phase of creating the revised theoretical framework utilised the research documented in chapter 7 on cardiovascular disease as an example of a long term condition. The use of quantitative analysis alongside qualitative analysis provided significant insight both on the use of technology and on the Lean non-value add activities emerging which are not identified in Lean literature. The underlying assumption of the initial framework was that by exploring the patients value stream across the silos of care providers, additional Lean wastes would be identified was proven to be correct. New non value-add activities representing the long term condition patient were identified and new areas for improving value were identified. Specifically the patient as co-creator of value emerged as a theme which is not covered in Lean healthcare, similarly the need to personalise messages to remove failure, a requirement to address prevention to remove demand and the patient value around medical decisions that may adjust the care requirement from treatment to management in end of life care, emerged as key areas from the empirical data and analysis. All of these areas built on the development of the initial framework but were discoveries of the research which developed the Lean knowledge. Additionally the use of technology to address the complexity of healthcare (Mazzocato et al., 2014) and personalise treatment for long term conditions (Holiday et al., 2015) emerged both as an opportunity to identify waste and also to improve value for the patient in the overall Lean process.

Figure 10.1 provides a theoretical diagram incorporating these points and reflecting an adaption of Lean to long term conditions where healthcare technology contributes to the identification of non-value add activities and creation of value.

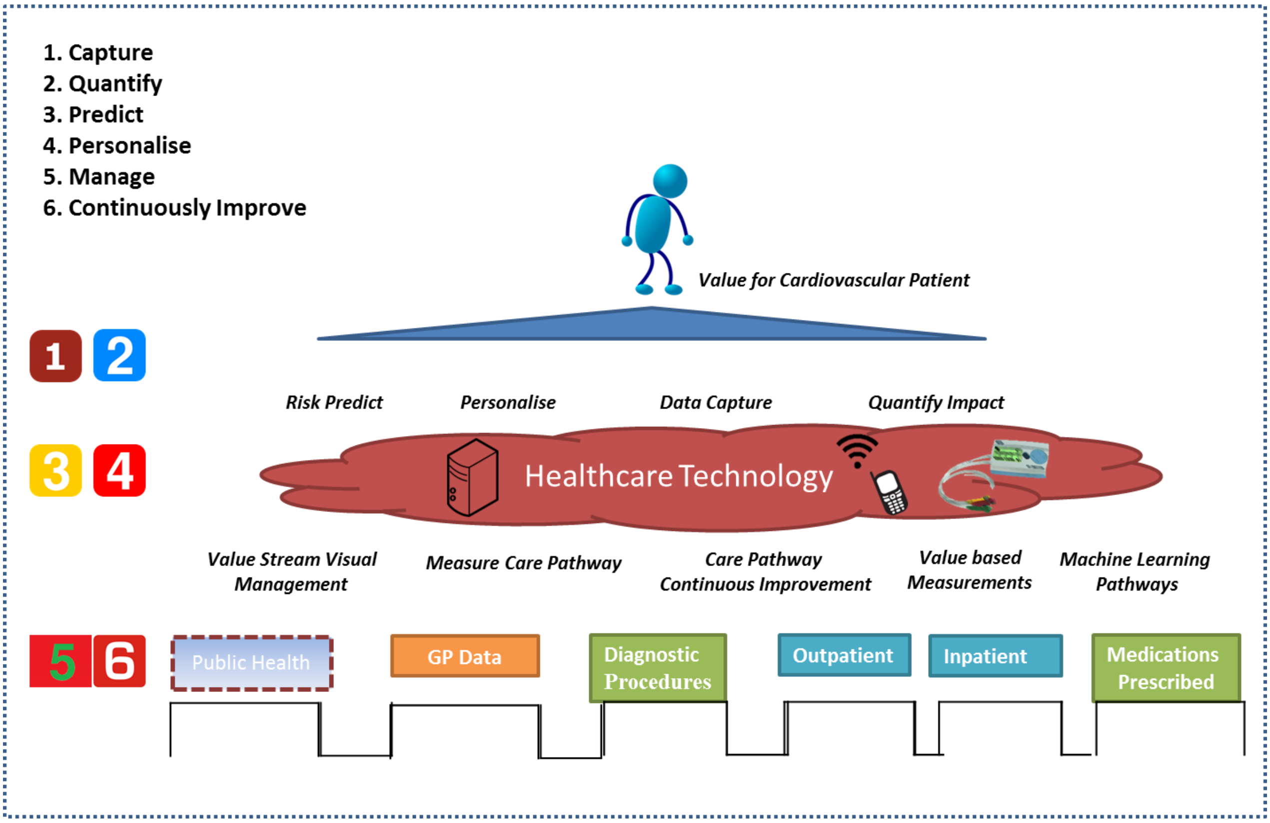


Figure 9.2 – Revised Theoretical Framework for Long Term Conditions

The six areas highlighted in the diagram represent a revision to the current method of addressing Lean healthcare and patient value. The first area of capture recognises that for many patients the data about their condition and disease and what represents value is not currently available. The research in chapter 7 identified that 1.3M days are utilised waiting on specific appointments and within this there is no data on the patient or changes to their condition beyond an initial referral letter. This is not addressed in Lean healthcare as a waste despite the high levels of unplanned admissions to hospital. Technology exists to capture and quantify patient conditions prior to seeing the clinician. The capture and quantification of live data could allow for prediction and personalisation utilising data analytics and machine learning as shown in Chapter 7 and 8. This prediction could highlight that patients exceeding a specific data threshold of a certain age is likely to end up in an ambulance in 48 hours and therefore intervene earlier to adjust medication, control the hospital admission or adjust the community treatment. Related to this is the ability to personalise messages based on the highest likely outcomes. If for example eating more vitamin C and taking your blood pressure medication is the target behaviour then personalisation of engagement to meet this outcome is possible through machine learning. For example the diet reminder could utilise an algorithm which calculates the times of the day where the patient is more vulnerable to abandon the diet or it utilises peer to peer support to produce better outcomes. Management and continuous improvement relate to the value stream as technology can assist in both providing visual management across the value stream and also in the management of the patients being progressed. Increase in demand and changes in patient behaviours were all evident in the chapter 7 and 8 analysis yet the clinicians were unaware of the overall impact or the root causes. In summary the theory building leading to the revised theoretical framework show that Lean and technology provide opportunities to learn, investigate and support continuous improvement, with key avenues for further research as discussed in Chapter 10.

9.3 Contribution to Knowledge

The thesis has made a contribution to Lean healthcare knowledge by identifying gaps and areas which are rarely addressed in Lean literature. The originality that the author has brought to the subject has been to connect healthcare, Lean and technology in a manner which has added to Lean theory and knowledge. A specific contribution to knowledge has identified a series of gaps for Lean healthcare which has application in developing Lean theory.

The principle finding that the research identifies is that Lean literature is focused on healthcare providers and not patients which is evident across the multitude of healthcare studies (Moraros et al., 2016). The majority of Lean literature represents an improvement initiative in a clinic, a pharmacy, ED, or other healthcare department. On occasion it addresses a hospital but rarely follows the patients journey (Manon, 2014). This gap is exacerbated when analysing a long term condition patients journey where the healthcare measurements starts and stops in line with the healthcare provider such as (section 7.5.3), turn-around times for diagnostic (section 7.4.3) and fails to address a full patient value streams from the initial referral to treatment or beyond. This failure to focus on the patient in Lean, results in waste being created in the handovers between healthcare providers and elements of the patient value stream is missing from Lean intervention.

A further contribution builds on Lean literature where it was stated that there is a lack of definition of what Lean is (Samuel et al., 2015). The lack of definition means that interventions can't be sufficiently measured and this will lead to a lack of quality evidence (Antony et al., 2016). Any criticism of the lack of Lean evidence is fair due to a lack of common approach that could allow deployments to be compared or validated against to ensure a deployment in implementing an effective approach rather than a "Lean" deployment by name only. Related to this gap of understanding what a complete Lean healthcare deployment should include, are two missing Lean principles of continuous improvement and patient value. There is a lack of understanding of the full value stream for the patient and what value for the patient means along this value stream. Continuous improvement can therefore only be applied in parts of the patient value stream which has been completed with some providers (Mannon, 2014). However this cannot address real value such as avoiding the need for treatment through prevention or personalisation of care to avoid inappropriate interventions which do not add value to the patient.

Linked to understanding the full patient focused value stream is a contribution to the lack of understanding of demand. Lean literature will focus on the ability of staff to cope with chaos in healthcare (Serr-Roszell, 2014) and building resilience in a system (Mannon, 2014) but fail to explore the possibility that the demand is not real demand but created by other failures in the value stream (i.e. failure demand, Seddon 2008). The research in 7.5.3 highlighted high levels of unplanned admissions and the qualitative analysis of spikes in outpatient waiting list revealed potential root causes being locum GP's over-referring due to inexperience or wanting to avoid any professional risk (appendix 4). Additionally, GP incentives in the system may be the root cause of referral spikes (appendix 4) yet the Lean healthcare literature does not address the potential for demand being avoidable. Thus healthcare may be creating a false demand in the system caused by the patient value stream creating wastes.

A further contribution is made in relation to Lean and technology. Lean literatures failure to be sustainable is an issue which leads to improvements that have been made, eroding over time rather than continuously improving or at least sustaining (McCann et al., 2015). The absence of technology in Lean literature is a gap as increasingly standards, processes and error prevention is either sustained or removed by technology. There is a contribution to knowledge in identifying the gap of why Lean does not utilise technology to identify waste, address waste, sustain improvement and deploy best practice. Due to the complexity and scale of healthcare this seems to be a significant defect in Lean application to healthcare if the intent is to improve patient outcomes.

These contributions have coalesced in leading to a contribution to theory using a theory building approach which builds further on the literature critique and initial theoretical framework (Chapter 5, Figure 5.3) The final theoretical framework (Figure 9.2) shows the key elements of this theoretical development and contribution. This includes the adaption of the value steam model utilised in Lean literature to apply to the whole patient pathway. The patient pathway should include prevention activities which are understood to stop a patient needing care and patient supporting activities such as medication and exercise which are essential to maintaining the health of a patient with a long term condition. This revised theoretical model covers a complex series of activities over a number of organisations and will benefit from the use of technology. The technology should be used with Lean principles to support visual management across the value chain and to build up an evidence base for analysis of live activities and root cause analysis to support continuous improvement. Technology should also be utilised for decision support to improve standardisation of best practice, personalisation of healthcare activities to maximise value for patients and the measurement of patient outcomes for healthcare activities and medicines.

9.4 Contribution to Practice

The thesis has made a contribution to practice in three key areas of; healthcare providers, industry and policy makers. This was completed by focusing on the research question of how can Lean be adapted for long term conditions? Can healthcare technology from data focused technology; assist in redefining patient value? And can healthcare technology assist in identifying and addressing Lean non-value add activities?

The research identified Lean healthcare wastes in chapter 3 and then developed these further based on knowledge contribution from the research in cardiovascular disease. 23 Lean waste areas in healthcare were identified throughout the thesis in areas such as waiting times, medication errors and repeated procedures which although known as waste in the healthcare literature have been developed further due to the application to long term conditions. What has also emerged as new contributions to knowledge are wastes such as prevention waste, public health waste, personalisation waste and social care waste which are not documented in Lean healthcare literature and have significant impact on healthcare practice. These reflect activities which do not add value or have not been addressed by activities within the value stream.

In the area of technology the thesis identified that healthcare is based on a series of decision and technology can capture and quantify data that is not available today to assist in making decisions earlier, faster and more accurately. This can both identify waste and increase value for patients in ways that are not addressed in Lean literature (Antoñanzas et al., 2016). In addressing the future of healthcare there is a drive towards preventative activities and self-management of many conditions (Ham, 2017) which will require engagement with patients in ways which are not possible today but can be addressed with technology. This can improve patient outcomes and remove waste in particular for an ageing population (Holliday et al., 2015). Technology also offers opportunities to predict patient behaviours and personalise intervention therefore removing the wastes of inappropriate interventions. Technology can address gaps in service provision such as understanding outcomes for medicines and other therapies (Antoñanzas et al., 2016). The contribution to practice focused on the capability of data technologies that could lead to continuous improvement and the reduction of waste if appropriately targeted. Technology alone can result in a technology push approach which fails to meet the needs of clinicians or patients however with the use of Lean to identify waste and deliver value there can be a more advantageous position for future healthcare and technology industries.

9.4.1 Implication for Healthcare Providers

At the beginning of the thesis, healthcare provision was stated to be under increasingly extreme pressure as people were living longer with multiple healthcare conditions (Dannapfel et al., 2014). The behaviour of patients however was not assisting in reducing the healthcare demand as low patient adherence to treatment and factors such as diet, alcohol and smoking were not being fully addressed (Moraros et al., 2015). The additional demand is resulting in an unsustainable cost inflation (Reijula et al., 2016). The thesis has revealed that healthcare providers are absorbing significant wastes which if identified and addressed could provide opportunities to address the additional demand and cost constrained environments. This could both improve patient outcomes and reduce costs per patient. The complexity and scale of healthcare, demands that technology should be used in conjunction with Lean to ensure sustainability of improvements and prevent initiatives being treated as temporary fads (McCann et al., 2015) and to enable effective decision support necessary for managing long term conditions. Additionally technology provides opportunities to address failures in adherence to treatment, lack of understanding of outcomes and behaviours through personalised approaches to treatment that utilised machine learning which focuses on positive patient outcomes.

9.4.2 Implication for Industry

The implications for industry are that healthcare is under cost pressure therefore all technology investments must address a business value for the organisation which has a significant return on investment. Lean can assist in identifying healthcare wastes which relate to business value and related costs. If wastes and quality issues can be addressed with technology, this creates compelling products and services for healthcare customers. These products and services will potentially lead to cost savings and improve patient outcomes which are jointly an attractive proposition for healthcare customers.

The healthcare wastes which have been identified could create a multitude of commercial products that will have financial success globally. Discussions with healthcare technology providers reveals a real interest in identifying evidence based insight on healthcare failures which could both assist in defining relevant products and also in assisting to tailor existing technology to specific healthcare needs. This level of detail is not available to companies and the evidence base behind this would be beneficial to industry as it relates back to specific healthcare providers globally.

9.4.3 Implication for Policy Makers

The implications for policy makers are that in cash constrained organisations the identification of waste creates an opportunity to improve outcomes and reduce budgets. The use of Lean across long term conditions is complex due to the scale but could be fruitful in developing better services. The use of Lean long term conditions also questions the commissioning choices which may need to be considered as it appears that decisions to intervene in specific areas is creating implications elsewhere. Technology that can assist in helping to understand these relationships would be worthwhile exploring further.

Appendix 6 provides examples where the outputs of the thesis and research finding are being used to influence the Northern Ireland Life & Health Sciences action planning, the UK Industrial Strategy Challenge Fund (ISCF) healthy Ageing agenda and smart city developments for Belfast. The underlying theme is that the economic growth of the Lean based technology businesses can lead to both economic growth and improvements in healthcare for citizens.

9.5 Implementation Considerations

Important question emerged in the qualitative analysis when attempting to validate the model with practitioners. Many of the healthcare improvement managers discussed how you could begin to implement such a model and what would be the key steps. An outline approach that has emerged from the analysis and qualitative analysis would include the following outline steps;

1. Identification of a medium to high risk patient group who have frequent engagement with the healthcare services.

2. Quantify patient focused measures on poor health outcomes to create a baseline which is currently not available - such as unplanned hospital admissions.

3. Identify relevant technology and service offerings that have a potential to contribute to patient value through earlier interventions that promote health.

4. Implement a new patient commissioning service that procures new services and technology to seek to deliver value based outcomes.

5. Implement technology that can measure the health outcomes and identify patients with escalating risk

6. Implement Lean continuous improvement based on new data from technology which focuses on patient value instead of interventions.

7. Implement machine learning to assist in understanding which combination of interventions lead to better outcomes.

The proposed model presents significant challenges for the current provision of care as it would require different ways of commissioning service providers, measuring activity and how services are delivered. It would be recommended that a demonstrator was established which allowed an ability to explore and compare a number of technologies and approaches in a controlled manner.

9.6 Conclusions and Recommendations

The key conclusion from this research is that Lean healthcare is focused on providers and not patient value which is counter to the principles of Lean. Long term conditions, such as cardiovascular disease, are a growing trend in healthcare demand and are these poorly served by provider or silo based healthcare systems represented in Lean literature. By focusing on Lean long term conditions, such as cardiovascular disease, wastes which are not reflected in current Lean healthcare literature can be identified across the patient value stream. Emerging technology which is often excluded from Lean approaches can assist in building visual management of the value stream, identifying waste and addressing this waste. As healthcare providers attempt to address growing elderly populations with increasingly complex needs (Hwang et al., 2014) while maintaining the buy in of staff (White et al., 2017) technology offers an opportunity to enhance visibility of data from the patient, provide decisions support for clinicians, to enable and empower staff and provide machine learning evidence based on patient outcomes.

Research question 1 asked how can Lean be adapted for Long Term Conditions and the thesis has shown that Lean can be adapted by returning to a core Lean principle of focusing on value for the customer, or patient in the case of healthcare, and moving away from short sighted organisation based improvements (McCann et al., 2015). Research question 2 asked how healthcare technology from data focused technology can assist in redefining patient value and the thesis has shown that firstly there is significant value not being delivered. Healthcare technologies can assist in addressing this. The redefined patient value stream, supported by technology, can deliver integrated care in a way which is often absent today and it can include opportunities for the patient to contribute to value creation through self-management technology (Ham, 2017). The focus on Lean and technology can also address barriers which have prevented better healthcare delivery by recognising that patient adherence to medicine, activity and diet result can be improve through personalisation of the engagement between the health providers and the patient. This will be particularly important in engaging with the needs of an ageing population with a growing number of long term conditions (Holiday et al., 2015). The third research question asked if health technology can assist in identifying and addressing Lean non-value add activities which the thesis has shown can be achieved by joining together the disconnected care pathway to provide a view of the patient's activities and non-value add activities. This provides healthcare leaders an opportunity to understand and address waste within the system to develop an evidence base for decision making and root cause analysis (Riezebos and Klingenberg's, 2009).

Answering these three research questions assisted in addressing the objectives of the thesis which led to the contribution to knowledge and practice outlined in section 9.2. The combination of meeting the research objectives and addressing the research questions has fulfilled the aim of the thesis by completing an exploratory study of healthcare technology development using a Lean thinking perspective.

9.6.1 Recommendations for Further research

The research focused on the use of cardiovascular disease as an example of a long term condition. This was necessary for the scope and timescales of the project; however the exploration of other long term conditions, such as diabetes, would be of value. Big data sets are available which would support this focus on other health conditions. It is expected that the knowledge and approach gained in this thesis has application and can be transferable to other chronic or long term conditions. Further research could explore if cardiovascular disease has unique characteristics or whether there are similarities in relation to other areas in terms of transferability. For example cardiovascular disease has a high average age for patients but other diseases, such as diabetes, which are also long term conditions, will have a different age profile for the patients and a different view of what value for a patient means.

Healthcare technology is exciting and interesting as novel technologies related to data, IOT, genomics and many other areas are emerging. These have the potential to revolutionise healthcare delivery and change the way that patients engage with the healthcare providers. These technologies are being developed and it is too early to understand their full potential. Given a period of maturity for these technologies it would be worthwhile to revisit the research and to explore how they can be integrated within a Lean approach. This may reveal a different model for Lean healthcare or a further refinement to the theoretical model.

The research focused on the use of the Northern Ireland healthcare service data. This is a public healthcare service which has specific characteristics on how patients consume healthcare provision. Further research could explore other UK geographies and healthcare providers which have alternative models of care provision in other global locations using the approach used in this thesis. A further limitation of the use of the Northern Ireland data was that this was data gathered from available open source data. This did not allow an ability to cross compare patient data as the linkage between activities and data sets was not available. Further research in partnerships with health providers could utilise real patient data and allow linkage between patient activities.

Finally, there is limited literature linking quality issues to cost beyond Spear (2005). Cost data was not available in the cardiovascular disease information in this thesis. Further research could quantify the cost of activities and importantly the cost estimates put on a waste. In an environment where technology must provide a return on investment justification, the cost of managing a waste would be a valuable measure and provide a new exploration on the role of technology in addressing healthcare challenges of cost and quality.

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Appendices

Appendix 1: Peer Reviewed Publications, Academic Conferences and Industry Publication

This appendix provides an overview of the formal dissemination that has taken place to date from the thesis.

Table A1.1 – Research Dissemination

Dissemination of Knowledge	Dissemination Type
International Conference on Engineering Technology and Innovation (IEEE), Belfast - June 2015	Peer reviewed submission: Conference presenter
European Lean Educators Conference – September 2016	Peer Reviewed Submission: conference presenter Lean Educators Conference - Presentation at the conference on the thesis topic – Participants at the conference include key Lean Educators such as John Seddon and John Bicheno and companies such as TWI.
Synnott, J., McComb, S., Nugent, C. and McLaughlin, J., 2015, December. NI-CHIC: A Model for Academic Engagement with Industry. In *Ambient Intelligence for Health* (pp. 258-263). Springer, Cham.	Published paper (contributing author)
Catherwood, P., McComb, S., Little, M. and McLaughlin, J., 2017, July. Channel Characterisation for Wearable LoRaWAN Monitors. In Loughborough Antennas and	Published paper (contributing author)

Propagation Conference (LAPC). IET.	
Microsoft Sponsored Roundtable Discussion on Transforming Healthcare with Leaders. Discussion recorded and published in magazine - Paul Duffy (Co-Director for IT and Telecommunications in the Belfast Health and Social Care Trust), Louise Skelly (Head of Operations at the Patient and Client Council), Sean Donaghy (Director eHealth at the Health and Social Care Board), John Woods (Chair of the Northern Ireland Council, British Medical Association) and Frank O'Donnell (Public Sector Lead for Microsoft Ireland)	Agenda NI Magazine: discussion article (grey literature) http://www.agendani.com/transforming-healthcare-in-northern-ireland/

Appendix 2: Qualitative Data - Northern HSC Trust Innovation Focus Group

This appendix provides an overview of the main qualitative data focus group meetings for the Northern Trust Innovation Group as explained in the research approach in section 6.3.

Meeting January 2015

Focus: Considering technology opportunities for community based long term conditions

Participants: Director of PCCOPS (NHSCT), Information Systems Project Manager (NHSCT), Assistant Director Person Centred Practice (NHSCT), Innovation & Development (NHSCT),Research Governance Manager (NHSCT), Project Manager TCC (NHSCT), Business Service Development & Governance Manager – Mental Health & Disability (NHSCT) and Researcher, Ulster University.

Discussion Notes: Discussion on the use of a report stating that 2/3 of the trusts resources were being used on 1/3 of the patients. Focusing on resource intensive patients was a relevant direction. Director reported on data analytics progress on an internal initiative application. There were discussions on regional interest in risk stratification which would identify high risk patients. There was further discussion on data analytics on regional data.

There was interest in domiciliary care use of technology for addressing areas of waste such as duplication, sharing best practice and sharing of information.

Discussions took place regarding the appropriate ethical consideration in trialing new technology. Partly this relates to patient ethics and partly with the procurements ethics due to working with commercial partners.

Discussions took place regarding the regional tele-monitoring contract and the possibility of any capacity within that contract to extend to include vital signs monitoring. Assistant Director (Person Centred Practice) discussed the “In-Reach” initiative into Nursing Homes. There was a potential extension of tele-monitoring within these homes.

February 2015

Participants: Performance Improvement Programme Manager (NHSCT), ICT Senior Manager (NHSCT),

Key discussion focused on outcomes for domiciliary care with long term conditions and frail elderly. There was a discussion on the use of apps within the care setting. “Long Term Care” pre-procurement competition (SBRI) was of interest to the Trust to explore technology to address their needs. Cognitive development and assessment of technology would be of interest due to the needs of dementia patients emerging with long term conditions. There was interest in Heart Failure care due to the volumes of patients and impact on hospital readmissions.

December 2016

Focus: Rapid Diagnostics in the Community

Participants: Northern Trust Representatives from Laboratories (David Farren), Reform (Gill Smyth) and community health (Karen Harvey). Local Commissioning Leads, Local GP representative and (Dr Ian Kernohan).

There was a discussion on rapid diagnostics technology and its use in primary care. Areas of interest expressed around the ability to complete the tests in the GP surgery that could prevent the need to send tests to the labs. GP concern of fitting this into workload but recognised they are already using resources in this area. GP interest areas would be UTI and CRP markers which link to the need for antibiotics. Commissioner interest expressed within rapid diagnostics for gestational diabetes monitoring in particular. Prototyping technology and the process of integrating this to patient pathways was a significant part of the conversation. The lack of resources available to explore new approaches was raised as a concern and governance issues such as validating the quality of any test would need to be addressed before starting any exploration.

Meeting June 2017

Focus: Diagnostics and use of Data in the Labs

Participants: Dr David Farren - Consultant Medical Microbiologist, Northern HSC Trust

Northern HSC Trust process 135,278 urine based tests a year. 30 % are from the hospital and 70% are from the community. 27% of UTI tests require culture analysis however 73% do not require further testing and could be tested with point of care devices. This data is important to understand the volumes going through the labs. It was also important to understand the volumes coming in from each GP as a change in process would impact the workload with the each practice as well. It was discussed that in many GP practices they are already doing some dip testing but they are still sending the test to the lab on a large number of occasions. This creates extra demand in the lab and a patient delay. Lack of transport from community to the lab over the weekend also emerged as a disconnect between community and diagnostics which is likely to result in weekend hospital admissions of patients who need a test.

GP Example discussed based on some numbers on the lab computer screens. 3500-4500 samples a year (*based on 2 practices,*20 a working day (*estimate*), unknown how many shouldn't have been sent and 44% from >65 age group*)*. Figure A2 created as a note to reflect discussion on the flow.

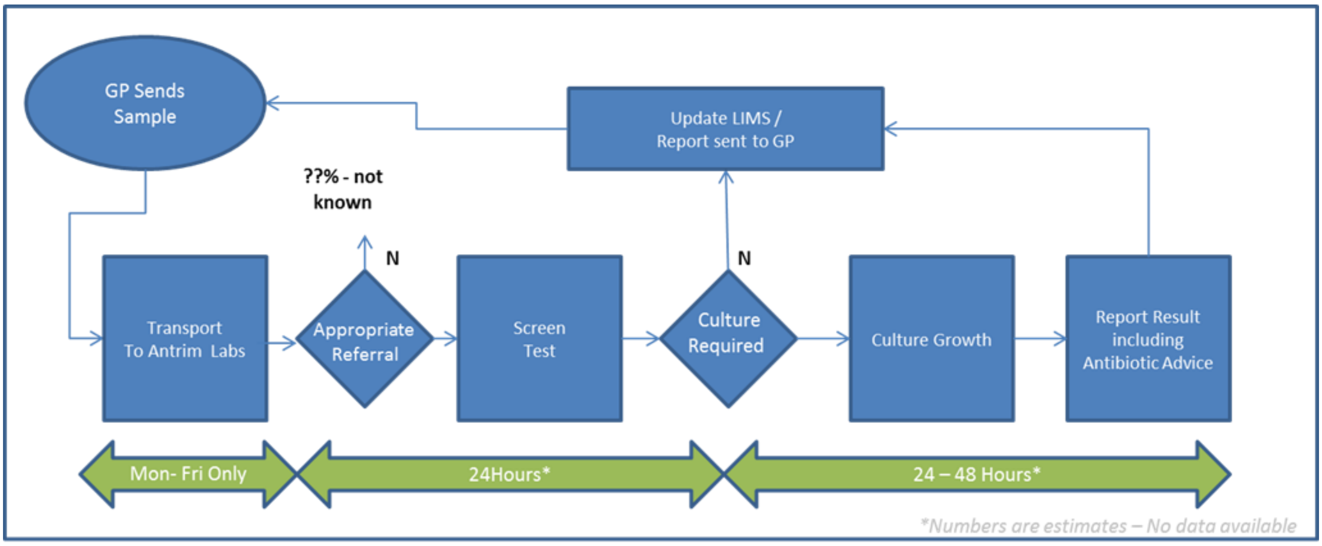

Figure A2.1 – Urine Based Test Flows and Timing

The known issues with the process are;

- Education: Lack of understanding on issues and confusion on issues such as foul smelling urine.
- Adherence to process: While there is guidance on when not to send a sample this is often not followed.
- Adherence to process: Dip tests are part of process but unclear of adherence levels.
- Adherence to process: Advice on pregnant woman, age of patient, asymptomatic patients, renal patients and catheter patients may not be followed or may not be commonly understood.
- Manual Error: Community dip tests may not follow process adequately but there is no method of identifying bad practice.
- Decision Support: Anecdotal evidence that a GP will send for test as a way of creating evidence trail for decisions.
- Test Availability: No tests from community received over weekend as delivery is Monday to Friday therefore a patient will likely be admitted to hospital at the weekend to allow tests to be performed.

Use of technology to address issues were discussed and it was agreed that electronic alternatives to dip test may provide evidence base required by GP therefore providing information for patient reassurance and decision making trail to protect GP from litigation.

Appendix 3: Qualitative Data - Cardiology Focus Group

This appendix provides an overview of the main qualitative data focus group meetings for the Cardiology focus group workshops as explained in the research approach in section 6.3.

April 2016

Focus: Use of technology in cardiovascular disease activity

Participants: Co-chairs of the cardiovascular network & Philips technology

The discussion focused on the Cardiology Network of Northern Ireland, heart failure and the reduction of hospital readmissions. Heart failure is recognised as a growing condition impacting a large number of patients either as a primary or secondary diagnosis. Discussions explored technology and healthcare interventions. The main areas of interest for using technology in cardiology included reducing heart failure readmissions, reducing average length of stay for heart failure and allowing intelligent monitoring of cardiology waiting-list patients to provide opportunities to escalate (reducing unplanned admission) and reassign patients to community services (reducing hospital attendance). As Philips were part of the discussions it was revealed that their CVIS system was in use across all 5 HSC Trusts in Northern Ireland. The implementations were independent implementations and data analytics although technically possible had some areas needing addressed as each implementation was not the exact same as Philips had essentially 5 separate customers. Governance over the sharing of data would need to be explored. Potential future interest includes

- Prediction/Risk Data Analysis
- Internet of Medical Things Devices
- Point of Care Diagnostic Readers
- Medication Optimisation
- Patient – Self Reporting
- Network Communications

- Ethics, Regulatory and Governance

Meeting June 2016

Focus: Use of technology in cardiovascular disease activity

Participants: Dr Patrick Donnelly, Professor Jim McLaughlin and the majority of PIs from the NI Clinical Research Network (4 out of 5 trusts represented)

There was a discussion on the use of technology to address heart failure gaps and failures. Debate on the figures for heart failure were inconclusive as there were a number of figure and some concern that the figures did not paint the complete picture. Discussions around the USA readmissions data were also debated as it was believed that local initiatives may have had a potentially beneficial outcome of reducing readmissions.

The thesis data around the care pathways was largely agreed to be new data to the cardiologists and most had not seen the open data available to the thesis. The area of comorbidities (multiple diseases) was relevant to the clinicians as some were becoming specialists in niches such as Cardiology and Cancer. Some examples of technology were discussed with a lot of discussion (and disagreement) on specific biomarkers used and their value.

Further discussion on predictive models, the value of specific markers and emerging technology. Topics such as patient engagement and empowerment were of less interest in the conversation and perceived to be dealt with by their nurses. Remote monitoring was of some interest although concerns about governance and expectation management to patients and hospital manager emerged as concerns.

March 2017

Focus: Use of Technology in Cardiovascular Disease Activity

Participants: Cardiologist Dr Patrick Donnelly, Dr Liam Burns (Connected Health Innovation Centre), and 2 Cardiac Lab Nurses in Ulster Hospital (names not available).

Significant fast paced discussion on heart failure and cardiac pathways and the consideration of novel technology for medication titration. Exploration of the impact of community based diagnostics for heart failure which could lead to further reduction in readmissions.

The emerging initiatives across the region utilising technology to develop intelligent data sets that could assist in understanding patients better were debated. There was some scepticism about the time available for clinicians to look at all the initiatives and the challenges of getting funding behind investments. Previous work he had been involved with had looked at the need for a patient disease register which has not been taken forward despite its value to cardiologists.

May 2017

Focus: Use of technology in cardiovascular disease – heart failure community nurse opinion

Participants: Charlie Ataliotis (Cardiac Nurse Specialist, Heart Failure Service, Downe Hospital) and Dr Liam Burns (Connected Health Innovation Centre).

There is an initial patient review appointment after about 2-4 weeks for most patients (mostly around 4 weeks). Some patients will take longer for first appointment depending on resource availability. Initial feedback from the HF nurse indicated that patients who are deemed to be more stable may be of lower priority and may be closer to 6 week before first appointment. This means that first appointment is beyond the time most published research highlights readmissions have occurred. In the discussions we did not have data on readmissions taking place prior to the first appointment. In the initial review a 12 lead ECG diagnostics test is completed. The HF team can read ECG's although they don't use them after the initial review unless there is a specific reason.

In reviews the main activities are

a. BP
b. ECG for initial Review - Pulse (simple HR number) for follow on reviews.
c. Respiratory rate
d. SPo2
e. Weight
f. Adema/Fluids
g. Bloods – Kidney function and BNP. BNP seen as a longer term chronic measurement and can guide therapy.
h. Respiratory/UTI Infections are not seen as their responsibility and they pass them on. Can have an impact on BP which can lead to HF.
i. Asthma – careful of beta blockers
j. Diabetes – careful of blood sugars
k. General questions on Sleep, exercise, Medication, Diet and fluids, alcohol reduction are discussed with the patient.
l. Temperature not a common measure. Pain not raised as a key measure.

After the initial review, the patient is met every 2-4 weeks until stable, then appointments reduced to 3 months medium term reviews and then 6 months long term reviews. Details of reviews main activities documented above still apply except in most cases the full ECG is not repeated at future appointments unless there is a specific reason such as AF. Palliative care spoken of frequently in discussions with the HF Nurse. Some clues about moving to palliative is dip in measures, more readmissions, more diuretics, age, patients view of aggressive treatment, LV function, chronic BNP. Left ventricle function measured through Echo if required

No data was collected outside of the times the nurse has visited and there may be value in more frequent monitoring. If technology could bridge this gap for escalation of declining patients then there is a potential for better health outcomes and the hospital could reduce readmissions. There is no data on the speed to stabilisation of HF medications. If for example a patient can be stabilised within 6 weeks instead of 12 weeks there could be both patient outcome benefits and capacity benefits. There is little data on the patients not receiving support as they are perceived to be stabilising. Monitoring these patients remotely with faster escalation routes due to profiling could be of value. These patients are off the radar of the specialist nurses and the only escalation route is unplanned admission.

February 2018

Focus: Specific discussion on the data emerging from the quantitative analysis

Participants: Cardiologist Dr Patrick Donnelly

Data emerging from the quantitative analysis was shared which showed a sharp rise in waiting list number around 2014. The discussion was to understand if there was a known underlying issue that would explain the rise. His response was that despite considering this overnight between receiving the information and the meeting there was no definite response that would immediately explain this. Two suggestions were put forward but he emphasised that these were suggestions. The independent sector supply had been reduced significantly around that time is one suggestion. Additionally a group of GP’s had retired around that time and the locums who replaced them would be more likely to refer as they did not have the experience or skills to make an informed decision locally. This also reflects risk avoidance by the locum. The discussion also considered possible ideas from the thesis research that GP incentives in the QOF may have encourage more GP’s to send patients for tests. He agreed this was a good hypothesis but admitted he had no detailed knowledge of GP QOF.

Appendix 4: Qualitative Data - Medicines Focus Group

This appendix provides an overview of the main qualitative data focus group meetings for the medicines focus group, as explained in the research approach in section 6.3.

April 2015

The thesis author led the establishment of the Northern Ireland Antimicrobial Resistance Network with Dr Patrick Dunlop (Ulster University). As part of the launch event a survey was made available to companies and researchers with one of the questions asking about the challenges (unmet needs) that the participants would like solved in the area of drug resistance.

Participants including DARD, HSC, CIGA Healthcare, Exploristics, Norbrook Laboratories Ltd, Public Health Agency, QUB, Randox Laboratories Ltd and Ulster University completed the questionnaire.

The responses are provided below and are relevant in understanding the challenges in medicines from both a government and industry perspective;

- Reliable platforms for discovery of lead compounds 2) Evidence base for antimicrobial selection clinically 3) Biofilm susceptibility analysis - still unclear if selection of antibiotics on the basis of biofilm susceptibility is a valid approach
- understand and counteract the bacterial stress responses upon chronic infection and sub lethal levels of antibiotics 2) find means to increase the permeability of the outer membrane to boost the antimicrobial efficacy of existing antibiotics
- Adoption, adoption, adoption. Randox already provide a 22 pathogen respiratory array for the correct identification of pathogens that cause respiratory infections including co-infections to ensure appropriate treatment is given. Also a 10-plex pathogen array is available for sexually transmitted infections. The 10 plex sexually transmitted infection array also identifies co-infections. Unidentified co-infections can

cause other problems including infertility which may require expensive IVF treatment in the future. Both are CE marked and provide results in 5 hours compared to the current >24 hours required to culture bugs but are not used by the NHS. Would HSC actually adopt a point of care analyser if it was available? 2. Improvement of HSC procedures (including allocating clinician time to research projects) to work with industry not only to be involved in research but to adopt new products developed through the research. Do we need to involve the decision makers at this early stage to identify the issues they face with regards adoption? 3. Identification/prioritisation of the most important health and environment issues to be addressed.

- Better and quicker methods to tell us if a patient has an infection or not. 2. Laboratory methods to detect AMR 3. New treatment options
- Access to data, collaboration with key stakeholders and access to funding
- cheaper, quicker diagnostics, reduced regulatory burden, greater funding for novel actives specifically for veterinary use
- Cost of point of care diagnostic devices Speed at which results can be obtained
- Faster & more accurate diagnostic tests that do not require bacterial culture... Reducing laboratory turnaround time (using existing tech.). Improved use of mobile / smartphone tech.
- Funding for research; better ICT systems to improve quality and value of surveillance; funding for initiation of the STAR implementation plan.
- I think that there needs to be representation on any future networking/collborations from GP's. Each Trust should have a Medical GP Director- Dr Brian Hunter represents the NHSCT and his role is to further develop links between General Practice and colleagues in Trust Services. There perhaps needs to be more education/training on responsible prescribing

- Improve empiric antimicrobial policy Improve antimicrobial stewardship Make better use of existing data
- Providing appropriate TAT for acute diagnostics providing molecular assays for AMR testing Integrating data generation and decision making
- Reduce bureaucracy. Increased access to: Funding Talented stakeholders (lab/clinicians/business/industry)
- The correct treatment Non prescribing when not required early identification of the particular condition or the make up of the ecosystem of infection
- understand levels of AMR in farmed animals in NI

Further AMR workshops have been held during 2017 and 2016. These have been of interest in the general context of healthcare but have not been documented due to not adding significantly beyond what has been stated above.

May 2016

Focus: Understanding Medicines and Technology

Participants: Cathy Harrison (Assistant Chief Pharmacist) and Professor Mike Scott (Medicines Optimisation Innovation Centre)

Topics discussed included the rising volumes of medicines and the falling prices. 2010 -2014. They shared that Lipid Regulating Drugs were known to come off a patent cliff during this period however the increase in Anticoagulants were the result of changes in NICE guidance. This is highlighted in a falling overall cost and the later years starting to rise again.

The second topic discussed was the role of the SBRI in looking for medication technologies. In their view, since they had begun an innovation quest with SBRI, the market had changed from very little available to quite a number of apps and technologies available. There was still however a gap for "solutions" rather than products. The search for solutions is evident in the use of SBRI's.

Appendix 5: Qualitative Data - Continuous Improvement Managers Clarification of Quantitative findings

This appendix provides an overview of the main qualitative data focus group meetings for the continuous improvement manager's clarification of quantitative findings. This reflects the approach explained in the research approach in section 6.3.

November 2017

Focus: Understanding the continuous improvement manager's response to the findings of the thesis. Gaining an insight into potential gaps in the thesis approach or analysis that has not been considered.

Participants:

Table A5.1 – Research Dissemination

Organisation	Name	Title
Public Health Authority	Jeni Rosborough	Cancer Screening Programmes Manager
Northern Health and Social Care Trust	Gemma Cameron	Team Leader
Business Services Organisations	Rachel McKibben	Customer Care & Performance Officer
Western Health and Social Care Trust	Michelle Kelly	Business Manager
Western Health and Social Care Trust	Bernie McCafferty	Strategic Change & Performance Manager
Western Health and Social Care Trust	Anne Donaghy	Directorate Business Manager

Southern Health and Social Care Trust	Yvonne Murphy	Senior OT
Southern Health and Social Care Trust	Alan Metcalfe	Assistant Director, Estate Services
Southern Health and Social Care Trust	Jacqueline Morton	Head of Continuous Improvement
Belfast Health and Social Care Trust	Natalie Magee	Senior Dementia Nurse Specialist
Belfast Health and Social Care Trust	Emma Ross	Family Nurse Supervisor
Belfast Health and Social Care Trust	Susanne McLaghlan	Business Support Manager
South Eastern Health and Social Care Trust	Helen Moore	Assistant Director of Performance, Improvement and Commissioning
South Eastern Health and Social Care Trust	Ruth Gray	Senior Dental Nurse
South Eastern Health and Social Care Trust	Scott Hyvart	Quality Improvement & Audit Facilitator
South Eastern Health and Social Care Trust	Justin Stephens	Organisation and Workforce Development
South Eastern Health and Social Care Trust	Damien Carson	Consultant Anaesthetist

During the workshop there was significant opportunity for exchanges of ideas and the key questions and outcomes were the following;

1. The health providers were surprised at the breadth of the data which was presented. They stated that they struggle within the health service to get access to that level of data and analysis. This highlights barriers to the data access and skills.
2. Many of the participants with experience of operational improvement were sceptical about the Lean literatures success as there was an underlying belief that the only “Lean” that gets published are the successful examples. Their view was that there was a publication bias as many attempts to implement Lean initiatives in healthcare had failed but they never became publications.
3. General agreement that by looking across the value chain of healthcare for long term conditions there was many opportunities for improvement. Within this, points about wastes within the system were agreed without challenge.
4. Specific agreement that commissioning decisions are being made without understanding the implications through the whole value stream and that systematically viewing the data across the full patient value stream may assist in addressing this.
5. The key discussion within the exchanges was however on the topic of sustainability. They recognised that although some success was made in Lean and other operational improvement initiatives this was not transferable and not sustainable. Time pressure, changing management personnel and attempting to survive between various crisis’s meant that sustainability was just not possible. Discussions about using technology to translate and sustain improvements were well received as a potential opportunity as many had seen improvements with initiatives such as the Regional Electronic Health Record. This system had shared information between professionals, saved lives and prevented operational waste such as phone calls, chasing up for data and duplicate diagnostic tests.

March 2018

South Eastern Health and Social Care Trust – "Curry Club"

The thesis author was invited to present the finding from the thesis and wider innovation to a senior gathering of the South Eastern Health and Social Care Trust at the "Curry Club". This event was run by the HSC's Trusts Chief Executive office. The event happened just after the thesis submission and before the viva for this thesis.

The presentation included;

- Challenges facing healthcare
- Technical opportunities
- Discussions on an alternative way of measuring patient value to allow services to be driven focus on patients
- Presentation on available data from the thesis
- Presentation on data that was not available but create value
- Presentation on what emergin technology could offer
- A proposed outline approach to taking the model forward

Feedback was positive with discussion around how much of the issues were falling budgets versus performance measures driving the wrong behaviour and resulting in missing patient value. Additional discussions emerged around prison healthcare being a potential candidate for early trials of new approaches.

Appendix 6: Qualitative Data – Significant Meetings and Conferences

This appendix provides an overview of additional qualitative data focus events and meetings that have contributed to the context of the thesis. Each of these reflects health, technology and process that have been relevant to the context of the thesis. In the majority of these the thesis author had a contribution or leadership role rather than a passive observing role.

Table A6.1 – Additional Significant Events and Meetings of Influence to the Thesis

Event	Participation	Benefit to Thesis
NI Life & Health Sciences Sector round table discussion. **January 2017**	NI Life and Health Science Leadership group including the Permanent Secretary for the Economy, Chief Medical Officer, UK Office of Life Science representative, Universities and Industry.	View on the future of Life and Health sciences and emerging technology interests.
Industrial Strategy Challenge Fund Workshops (Follow on to Prime Ministers Statement).	Select group of NI Industrial and Academic leads with Government representatives from Invest NI and Innovate UK. Innovate UK leader of Life and Health Science, Dr Ian Campbell took part.	Workshop to distil and consult on the future UK direction for supporting innovation. Specific interest in future Health Technology Growth discussed.

January 2017		
Data Analytics Workshops **June 2014** ***(Following 2 Additional Sessions Discussing Health Analytics)***	HSC, BSO, Accenture, Aridhia, Kainos and Boehringer Ingelheim.	6 companies and 2 Universities were provided data from across the HSC to explore the health services understanding of the possibilities of healthcare analytics and machine learning. Key discoveries were that there are significant capability gaps in the health service in data analytics and change management.
Smart City Belfast Workshop **March 2017**	Hosted in partnership with the Future Cities Catapult and attended by government industry, council and other stakeholders.	Insight on emerging technology interests impacting health in a city and health inequalities.
Ulster University Health Sandpits for Mental Health and	Two interdisciplinary gathering of academics with a focus on Mental Health and Public Health led by the PVC of research.	Debate and discussion on the merits and demerits of technology, public policy and future interventions. Also discussions on emerging themes and research interest.

Public Health **March 2017**		
IOT Healthcare Focus **January 2017**	55 Participants from technology companies including Intel and Aepona and partnered with the IOT Alliance. Speakers included Colin MacHale, Director Health and Life Science EMEA, Intel Corporation, Dr Philip Catherwood (UUJ) and Prof Jim McLaughlin (UUJ). Event organised by thesis author with IOT Alliance.	Informed view on emerging technology.
SBRI NHS England Reviewer **December 2016**	Assessment of 15 applications to the NHS England competition on cancer and patient flow.	December 2016 – Assessment of SBRI procurements.
NI Life and Health Science Action Plan **Mid 2016 -**	Permanent Secretary of Health, Permanent Secretary of Health, Invest NI CEX, Chief Medical Officer, ABPI, Randox, Almac, O4 Research, QUB, UU and other officials.	Confidential discussions and report contribution, related to the future of Health and Life Sciences in Northern Ireland. Relates to future technology development and adoption in

January 2017		Healthcare. Outputs ongoing and not publically available yet.
EHI Live Birmingham (Largest Health Tech Conference in UK) **Nov 2016**	Targeted at health ICT leaders. Event attended with David Watwood (CIGA Healthcare), Leeann Monk (Elemental Software), Deepak Samson (Connected Care Solutions), Gareth Morrison (Lava Group). The event has a mixture of company displays and various talks from health leaders who were mainly NHS England related.	Topics of interest to the thesis included: personalisation in healthcare in line with the Sustainability and Transformation Plan (STP) from NHS England, data mining patient notes with natural language processing, data for forecasting, Wearable interest but recognition of poor quality inappropriate for clinical relevance in ageing population.
E-Health Ireland and Northern Ireland **December, 2016**	Targeted at academia, business and health technology in Northern Ireland and Southern Ireland	Attended event to discuss various health technology opportunities and view demonstrators.
World Innovation Summit for	Event attended with permanent secretary Dr Andrew McCormick. Invitation only event for healthcare leaders. Meetings	Areas of significance in the meeting with the various stakeholders included; chronic

Health: Doha, Quatar **November 2016**	included: - Healthcare UK - COO (Ilaria Regondi) and MD (Deborah Kobewka) - Abbvie – Focus on Drug Therapies - Novartis – Drug Therapies. Some interest in Drug Trials around Diabetes and Chronic Conditions - - Teradata – CTO – Stephen A Brobst – - McKinsey – Healthcare Consultant - Hamad Medical Corporation - British Heart Foundation - Otta Project – Cerebral Palsy support product – - Express Healthcare – India Journalism - AMMI – pregnancy educator for rural illiterate Pakistan - Proximie – Augmented Reality Surgery - 'Bac-Kits', - AMR Focus	condition management, patient behaviour, use of data, infectious diseases, drug resistance, and genomics. The first three being of direct relevance to the focus of the thesis.
Health and Economic Growth in the Sister Cities of Boston, Nashville	Companies participating; Lucro, CIGA Healthcare, Shimmer Sensing, Momedx, Analytics Engines, See.Sense, GoWalkTalk, MyWoundDoctor, Santovia, Moveo, Kainos, Digital Catapult, NI Connected Health Innovation Centre, Belfast City Council, City of Boston,	Focus on Health and Economic Growth in the Sister Cities of Boston, Nashville and Belfast. Main areas of common interest included; Connecting economic innovators in the area of Digital and Healthcare Technologies,

and Belfast – October 2016	ARCH, Ulster University, Nashville Metro Council and Chris Cunningham Organised and led by thesis author with participating councils (mainly Belfast CC).	utilising data in novel ways to create data rich conversations which lead to better city management, economic opportunities and improvement of health for citizens. Addressing health inequalities through data and technology.
Partners Healthcare Symposium, Boston	Connected Health Conference	Discussion and Presentations on Health Technology use from American perspective.
Digital Catapult	Tom Gray (Digital Catapult Leader for Northern Ireland)	Sept 2016 – Meeting with Digital Catapult Leader to discuss healthcare technology.
Industrial Strategy Challenge Fund Workshops – Healthy Ageing workshop	Workshop led by Dr Ruth McKernan – CEO of Innovate UK on behalf of innovate UK and Research Council UK.	Confidential (at time) workshop to guide future government strategy on funding for Industrial Strategy Challenge Fund. Healthy Ageing was bidding within government to prioritise funding in midst of 10 other options.
Healthcare Innovation	Healthcare Leaders from across all 5 HSC trusts in Northern Ireland.	Successful application to most innovative use of technology

Award – February 2017		for 2017.
Longitude Prize workshop in London **September 2017**	Nesta Longitude Prize competitors and leaders.	Discussions on a £10m award to tackle AMR resistance.
End of Life Manchester **December 2014**	Manchester AHSN. This included palliative and end of life specialists from clinical, service improvement, quality improvement, social work, care facilitators, commissioners, ICT, Data analysts and the third sector organisations	The workshop, led by the thesis author, utilised a Lean and system thinking approach of aligning resources to patient value where there is interaction between a patient and care delivery organisation

Appendix 7: Qualitative Data – Significant Meetings and Conferences

This appendix includes specific technical details that are referenced throughout chapter 7. To aid the flow of the thesis for the reader they have been included in the thesis for reference with a relevant table reference number which is referred to in chapter 7.

Table A7.1 – GP Quality Outcomes Framework Data

QOF Indicator Area	QOF Code	Description	Patient Number For NI
AF	AF002	The percentage of patients with atrial fibrillation in whom stroke risk has been assessed using the CHADS2 risk stratification scoring system in the preceding 3 years (excluding those whose previous CHADS 2 score is greater than 1)	29,901
AF	AF005NI	In those patients with atrial fibrillation in whom there is a record of a CHADS 2 score of 1 (latest in the preceding 3 years), the percentage of patients who are currently treated with anti - coagulation drug therapy or antiplatelet therapy	6,761
AF	AF004	In those patients with atrial fibrillation whose latest record of a CHADS 2 score is	13,479

		greater than 1, the percentage of patients who are currently treated with anti-coagulation therapy	
Heart Failure	HF002NI	The Number of patients with a diagnosis of heart failure (diagnosed on or after 1 April 2006) which has been confirmed by an echocardiogram or by specialist assessment between 3 months before and 15 months after entering on to the register	9,842
Heart Failure	HF003	In those patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction, the percentage of patients who are currently treated with an ACE - I or ARB	3,116
Heart Failure	HF004	In those patients with a current diagnosis of heart failure due to left ventricular systolic dysfunction who are currently treated with an ACE-I or ARB, the percentage of patients	2,553
		who are additionally currently treated with a betablocker licensed for heart failure.	

Table A7.2 – Cardiovascular Disease in the Context of Healthcare Activity (Source Data: Department of Health, 2017, Inpatient and Day Case Waiting Times)

Title	Number	%
General Medicine	120,505	19.3
Nephrology	96,831	15.5
General Surgery	80,171	12.8
Cardiology	**35,358**	**5.7**
Gastroenterology	34,969	5.6
Urology	27,697	4.4
Paediatrics	24,968	4.0
T&O	24,243	3.9
Haematology Clinical	21,243	3.4
Thoracic Medicine	19,338	3.1
Gynaecology	17,660	2.8
Ophthalmology	17,562	2.8
Clinical Oncology	17,011	2.7
ENT	14,116	2.3
A&E	10,836	1.7
Medical Oncology	9,109	1.5
General Practice Other	7,120	1.1
Dermatology	6,288	1.0
Plastic Surgery	5,846	0.9
Rheumatology	4,926	0.8
Pain Management	4,512	0.7

Oral Surgery	4,394	0.7
Neurology	3,770	0.6
Endocrinology	3,420	0.5
Rehabilitation	2,354	0.4
Neurosurgery	2,351	0.4
Paediatric Surgery	2,218	0.4
Anaesthetics	2,041	0.3
Thoracic Surgery	1,418	0.2
Cardiac Surgery	**1,151**	**0.2**
Palliative Medicine	622	0.1
Paediatric Dentistry	445	0.1
Radiology	340	0.1
Paediatric Neurology	237	0.0
Restorative Dentistry	205	0.0
Infectious Diseases	131	0.0
Genito-urinary Medicine	37	0.0

Table A7.3 – Prescription Cost Pareto Analysis Identifies 3 Drugs in 79% of Costs (Developed from Source Data: BSO Pharmaceutical Statistics, 2018)

Drug	Total Qty	Total Ingredient Cost (Before Discount)	% of Total Cost	Pareto Analysis
Apixaban	**6114028**	**5991440.928**	**43.60**	**43.60**
Rivaroxaban	**1781404**	**3202830**	**23.31**	**66.91**
Enoxaparin	**328258**	**1708750.151**	**12.43**	**79.34**
Coaguchek	290838	829648.858	6.04	85.38

Dabigatran	681703	593414.108	4.32	89.70
Warfarin	16542783	540523.883	3.93	93.63
Clexane	63446	291508.472	2.12	95.75
Eliquis	245247	238640.239	1.74	97.49
Xarelto	51841	93062.7	0.68	98.16
Edoxaban	34363	63571.55	0.46	98.63
Phenindione	2823	52425.125	0.38	99.01
Pradaxa	48834	41508.9	0.30	99.31
Lixiana	18107	34737.2	0.25	99.56
Heparin	13260	21581.333	0.16	99.72
Fragmin	2883	14734.85	0.11	99.83
Arixtra	979	8183.887	0.06	99.89
Alere	2866	7167.972	0.05	99.94
Innohep	1158	6022.126	0.04	99.98
Tinzaparin	422	1596.185	0.01	99.99
Dalteparin	60	338.73	0.00	100.00
Acenocoumarol	6288	290.511	0.00	100.00
Sinthrome	1612	74.484	0.00	100.00
Marevan	1080	11.957	0.00	100.00

Figure A7.1 – Representation of Cardiology Medicine Definitions with the BNF – (Open Prescribing, 2017)

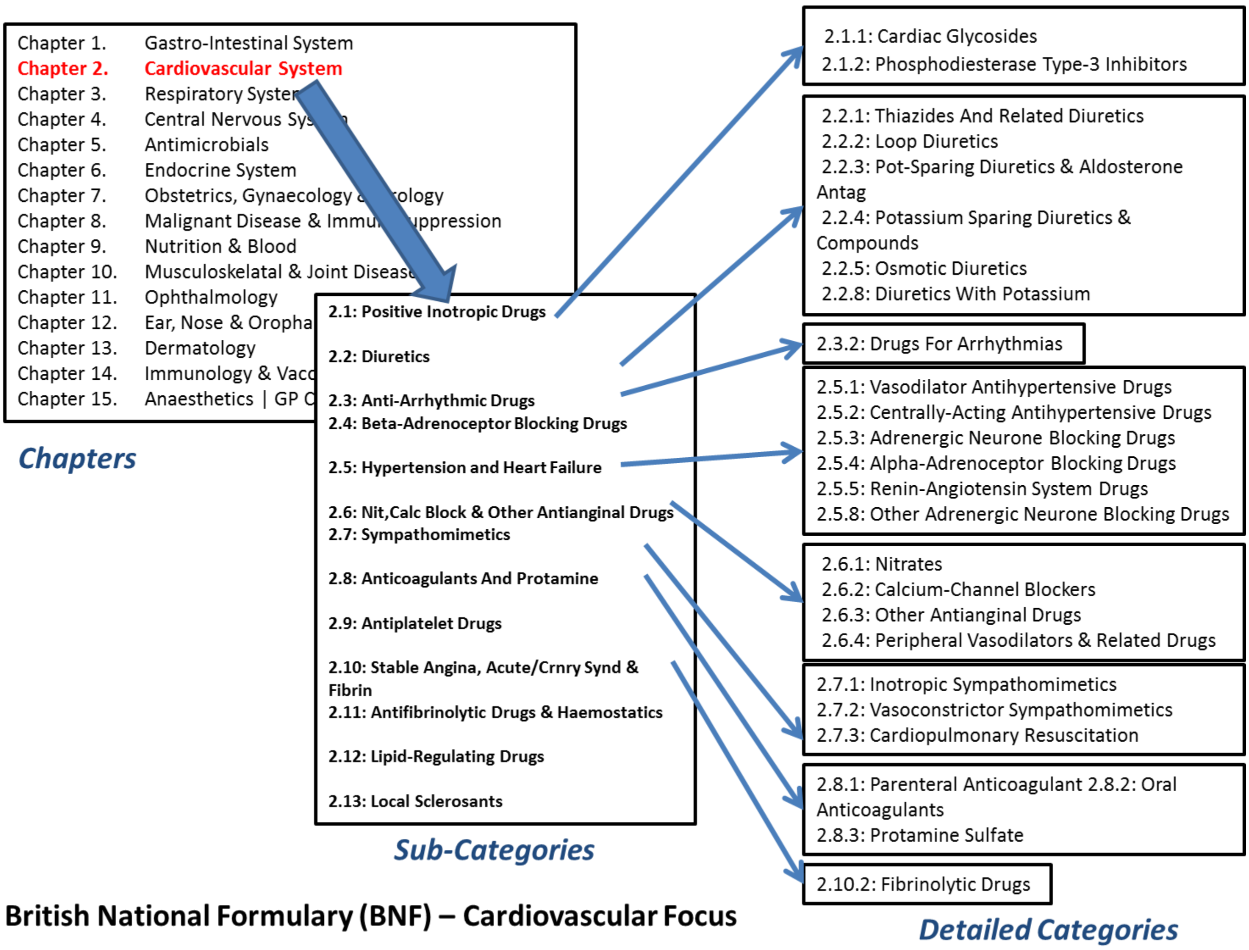

Table A7.4 –Prescription Cost Analysis Northern Ireland 2016 (Developed from Source Data: BSO Pharmaceutical Statistics, 2018)

BNF Chapter Name	BNF Chpt,	Number of Prescription Items	Ingredient Cost (Before Discount))	% of Total Volume	% of Total Cost
Gastro-intestinal system	1	3,952,729	21,851,486.881	9.54	4.98
Cardiovascular system	2	9,136,162	52,013,780.272	22.05	11.86
Respiratory system	3	3,143,509	47,431,180.307	7.59	10.82

Central nervous system	4	10,301,746	109,966,070.653	**24.86**	**25.07**
Infections	5	2,190,320	10,949,460.972	5.29	2.50
Endocrine system	6	3,324,681	55,871,279.594	8.02	**12.74**
Obstetrics,gynaecology & urinary-tract disorders	7	1,077,645	17,758,153.098	2.60	4.05
Malignant disease & immunosuppression	8	158,839	10,443,934.368	0.38	2.38
Nutrition & blood	9	1,861,431	30,409,191.792	4.49	6.93
Musculoskeletal & joint diseases	10	1,571,300	11,048,369.266	3.79	2.52
Eye	11	646,590	4,784,903.319	1.56	1.09
Ear, nose & oropharynx	12	719,551	4,408,862.943	1.74	1.01
Skin	13	2,185,639	17,262,504.032	5.27	3.94
Immunological products & vaccines	14	42,875	984,878.144	0.10	0.22
Anaesthesia	15	65,971	2,819,880.327	0.16	0.64
Other drugs & preparations	19	694	3,095.228	0.00	0.00
Dressings	20	454,435	9,242,133.252	1.10	2.11
Appliances	21	180,918	6,459,709.559	0.44	1.47
Incontinence appliances	22	57,725	1,662,755.182	0.14	0.38
Stoma appliances	23	117,467	8,791,331.123	0.28	2.00
Unclassified	99	249,154	14,400,306.197	0.60	3.28
Totals		**41,439,381**	**438,563,266.51**		

Table A7.5 – Emerging Healthcare Innovations related to Cardiovascular Disease (Source Data: Innovate UK, 2017)

ID	Project Title	Lean Failure or Opportunity this Addresses	Competition Year
1	A Deep Learning Algorithm To Eliminate Errors During Fractional Flow Reserve	Measurement errors by cardiologists	2017/18
2	Kiosk Automated Screening Cardiovascular Performance - KASC-P	Screening for specific cardiac problem	2017/18
3	High Sensitivity Chemiluminescent Point of Care Tests for Cardiac Troponin	Remove wait for tests by using point of care testing	2016/17
4	Patient-Specific Simulation of the Heart Organ for Diagnosis	Better training – Failure in training	2015/16
5	Development of a 4Mhz suprasternal Doppler probe for cardiac output measurement	Clinical measurements	2015/16
6	Non-Invasive Continuous Physiology Monitor (NCPM)	Continuous diagnostics monitoring of vital signs	2015/16
7	In car Health Monitor	Heart attack drivers	2015/16
8	ICURE Aid for Start Ups Cohort 3	Medical implants	2015/16
9	Clinical Proof of Concept of Agluna Silver Antimicrobial Cardiac Pacemakers	Infection	2014/15
10	Wearable Acoustics	Novel feedback	2014/15
11	Renephra Ltd. Validating commercial opportunity for a novel medical device to treat fluid overload	Clinical fluid balancing	2014/15

12	InoCardia: Cellular Work-Loop Proof of Concept	Adverse Drug impact measure	2014/15
13	Guide Cardiac Resynchronisation Therapy - Guide CRT	Non-responders to treatment	2013/14
14	Predictive phenotypic assays to better predict drug-induced cardiotoxicity	Predict drug effectiveness	2013/14
15	A high resolution gamma camera for earlier tumour detection	Imaging related	2013/14
16	Heart Simulator for Training and Diagnosis Support	Training simulation	2013/14
17	The Combined Catheter: Integrating drug delivery and pressure measurement to improve stratification of therapy in patients with coronary artery disease.	Personalising (Stratifying)Therapy	2013/14
18	Demonstration of a low cost implantable blood pump	Implantable device	2012/13
19	New Technology of Navigation and Guidance in Cardiac Arrhythmias	Clinical Guidance	2012/13
20	Diasolve Investigation of Market Potential for a Novel Vasodilator and Delivery Device for use in Cardiac Stress Testing and Stenting	Cardiac Devices	2011/12
21	New drug dosage formula for the treatment of hypertension and heart failure in children	Safe drug delivery addressing medicines failures in children	2011/12
22	Real-time Simulation of Cardiac Electrophysiology for Medical Training and Diagnosis Support - Epicardio Ltd	Training and support	2011/12
23	Demonstration of the potential application of Agluna anti-infective surface treatment technology to cardiac pacemakers	Surface treatment to address infection	2011/12
24	Magnetic lab-on-chip devices for	Rapid diagnostics	2011/12

multiplexed clinical diagnostics